

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

MASSACHUSETTS INSTITUTE OF  
TECHNOLOGY,

Plaintiff,

V.

HARMAN INTERNATIONAL INDUSTRIES,  
INCORPORATED,

Defendant.

Case No.: 05-10990-DPW  
ORAL ARGUMENT REQUESTED

**HARMAN’S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION  
FOR SUMMARY JUDGMENT OF UNENFORCEABILITY  
DUE TO MIT’S INEQUITABLE CONDUCT**

## TABLE OF CONTENTS

	<u>Page</u>
<b>I. MIT’s Arguments About The “Limited, Controlled Distribution Of Jim Davis’ Thesis” Are Contrary To Law .....</b>	<b>3</b>
A. MIT’s Misrepresentation That The Thesis Was Not Publicly Available Prior To The Critical Date Was Material As A Matter Of Law. ....	4
B. MIT’s Declarations, As A Matter of Law, Create No Issue Of Material Fact.....	7
C. Davis’ Public Defense Of His Thesis Was Also Material As A Matter Of Law. ....	9
D. MIT Intentionally Deceived The PTO When It Knew Of But Deliberately Did Not Disclose The Availability Of The Davis Thesis .....	10
<b>II. MIT’s Argument That The 50 Uses Of “The Patentable Invention” WERE “Immaterial” And “Cumulative” Is Wrong As A Matter Of Law .....</b>	<b>12</b>
A. The Information That MIT Withheld About The 50 Public Uses Of “The Patentable Invention” Was Material. ....	14
B. The Information That MIT Withheld About The 50 Public Uses Of “The Patentable Invention” Was Not Cumulative. ....	16
C. MIT Intentionally Deceived The PTO When It Knew Of, But Deliberately Did Not Disclose, The 50 Public Uses Of “The Patentable Invention.” .....	18
<b>III. Conclusion .....</b>	<b>19</b>

## TABLE OF AUTHORITIES

	<u>Page(s)</u>
<b>Federal Cases</b>	
<i>Agfa Corp. v. Creo Prods. Inc.</i> , 451 F.3d 1366 (Fed. Cir. 2006).....	5, 9
<i>Allen Eng'g. Corp. v. Bartell Indus., Inc.</i> , 299 F.3d 1336 (Fed. Cir. 2002).....	12, 15
<i>Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.</i> , 731 F.2d 831 (Fed. Cir. 1984).....	1
<i>Baxter Intern., Inv. v. COBE Labs., Inc.</i> , 88 F.3d 1054 (Fed. Cir. 1996).....	16
<i>Bernhardt, LLC v. Collezione Europa USA, Inc.</i> , 386 F.3d 1371 (Fed. Cir. 2004).....	15, 16
<i>Cargill Inc. v. Canabra Foods Ltd.</i> , 476 F.3d 1359 (Fed. Cir. 2007).....	4, 17
<i>Constant v. Advanced Micro-Devices, Inc.</i> , 848 F. 2d 1560 (Fed. Cir. 1988).....	5
<i>Critikon, Inc. v. Becton Dickenson Vascular Access, Inc.</i> , 120 F.3d 1253 (Fed. Cir. 1997).....	18
<i>Digital Control Inc. v. The Charles Mach. Works</i> , 437 F.3d 1309 (Fed. Cir. 2006).....	3
<i>Egbert v. Lippmann</i> , 104 U.S. 333 (1881).....	14
<i>eSpeed, Inc. et al. v. Brokertec USA, L.L.C.</i> , No. 2006-1385, 2007 WL 817665 (Fed. Cir. March 20, 2007).....	11
<i>Hall v. Macneale</i> , 107 U.S. 90 (1883).....	14
<i>In re Epstein</i> , 32 F.3d 1559 (Fed. Cir. 1994).....	14
<i>In re Klopfenstein</i> , 380 F.3d 1345 (Fed. Cir. 2004).....	5, 6, 16
<i>In re Metoprolol Succinate Patent Litig.</i> , No. MDL NO. 1620, 2006 WL 120343, (E.D. Mo. Jan. 17, 2006).....	7

**TABLE OF AUTHORITIES (cont'd)**

	Page(s)
<i>Invitrogen Corp. v. BioCrest Mfg., L.P.</i> , 424 F.3d 1374 (Fed. Cir. 2005).....	14
<i>LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n</i> , 958 F.2d 1066 (Fed. Cir. 1992).....	4
<i>Li Second Family Ltd. P'ship v. Toshiba Corp.</i> , 231 F.3d 1373 (Fed. Cir. 2000).....	2
<i>Life Techs. Inc. v. Clontech Labs., Inc.</i> , 224 F.3d 1320 (Fed. Cir. 2000).....	2
<i>Lough v. Brunswick Corp.</i> , 86 F.3d 1113 (Fed. Cir. 1996).....	14
<i>Mass. Inst. Tech. v. AB Fortia</i> , 774 F.2d 1104 (Fed. Cir. 1985).....	4, 6
<i>McKesson Info. Solutions, Inc. v. Bridge Med., Inc.</i> , No. 2006-1517, 2007 WL 1452731, (Fed. Cir. May 18, 2007) .....	3
<i>Molins PLC v. Textron, Inc.</i> , 48 F.3d 1172 (Fed. Cir. 1995).....	11
<i>New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.</i> , 298 F.3d 1290 (Fed. Cir. 2002).....	13
<i>NTP, Inc. v. Research In Motion, Ltd.</i> , 418 F.3d 1282 (Fed. Cir. 2005).....	14
<i>Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.</i> , 984 F.2d. 1182 (Fed. Cir. 1993).....	11
<i>Refac Intern., Ltd. v. Lotus Dev. Corp.</i> , 81 F.3d 1576 (Fed. Cir. 1996).....	11
<i>Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.</i> , 204 F.3d 1368 (Fed. Cir. 2000).....	11
 <b>Federal Statutes</b>	
Fed. R. Civ. P. 56(e) .....	1, 10
Fed. R. Evid. § 801(d)(2)(A) .....	9
MPEP 2004 ¶ 11 (5th Ed. 1983) .....	17

In its opening brief, Harman established by clear and convincing evidence that MIT engaged in two separate instances of inequitable conduct during prosecution of U.S. Patent No. 5,177,685 (the “’685 patent”). Each instance separately compels the conclusion that the ’685 patent is unenforceable. *First*, MIT committed inequitable conduct when it affirmatively misrepresented and concealed the availability of Davis’ thesis—in MIT’s words, the “limited, controlled distribution of Jim Davis’ thesis” (MIT’s Opposition Brief at 2 (“Opp.”))—after the PTO Examiner expressly found it invalidated every claim of the ’685 patent. *Second*, MIT committed inequitable conduct when it deliberately withheld information about the 50 people who used “the patentable invention” before the critical date. Opp. at 10.

MIT’s opposition is full of rhetoric and unsupported attorney argument but presents no “specific facts showing that there is a genuine issue for trial” for any of the misrepresentations and omissions Harman identified. *See* FED. R. CIV. P. 56(e) (“an adverse party . . . must set forth specific facts showing that there is a genuine issue for trial.”) Even a cursory review of MIT’s “Counter-Statement of Facts” (“CSOF”)<sup>1</sup> reveals that MIT’s supposed “disputes” are nothing more than general, unsupported denials that cannot defeat Harman’s motion for summary judgment. *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984) (“[T]he court may not simply accept a party’s statement that a fact is challenged.”)

Nevertheless, MIT erroneously falls back on conclusory assertions and argues “as a matter of law” that those misrepresentations and omissions were either immaterial or unintentional. Opp. at 6, 14. Yet, MIT made no effort to acknowledge, let alone distinguish, the overwhelming legal authority supporting Harman’s motion on either point. *See* Harman’s

---

<sup>1</sup> For clarity, Harman’s Statement of Facts (“HSOF”), MIT’s Statement of Facts (“MSOF”), and MIT’s Responses to Harman’s Statements of Fact, also called MIT’s Counter-Statements of Facts (“CSOF”), are all collected together in Harman’s Response and Reply SOF, filed with this brief.

Opening Brief at 8-9, 13, 15-16, 19.

The most striking thing about MIT's opposition is the extent to which MIT tries to divert the Court's attention away from the undisputed evidence of MIT's intentional misconduct by arguing that the information it admittedly withheld was material only if it was invalidating prior art. That argument is contrary to the applicable law, which MIT also fails to address. *See Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000) (finding materiality when "a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability"). As MIT well knows, information is "material when there is a substantial likelihood that a reasonable Examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Opp.* at 4 (citing *Life Techs. Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000)). Indeed, "whether the information would conclusively decide the issue of patentability" is neither the relevant inquiry nor is it an issue presently before this Court. *Li Second Family*, 231 F.3d at 1380. Under the correct materiality test, MIT's misrepresentations and omissions were material.

Instead of coming forth with record evidence, MIT argues around the substantial evidence of its intent to deceive with a blanket assertion that "Harman can offer no evidence." *Opp.* at 19. Ignoring the considerable evidence Harman presented of MIT's deceptive intent does nothing to contradict it. *See HSOF* 16-23, 28-30, 33-38, 57-59.

In short, Harman's motion presents a straightforward issue; one that MIT has done all it can to obfuscate. MIT admits that the same thesis that led to the initial rejection of MIT's August 1990 patent application was (i) distributed to third parties prior to the August 1989 critical date, and (ii) was publicly defended in the "late summer of 1989." The material facts are

undisputed. All that remains is a question of law for the Court: “whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with greater showing of one factor allowing a lesser showing of the other.’” *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, No. 2006-1517, 2007 WL 1452731, at \*13 (Fed. Cir. May 18, 2007) (attached as Ex. 45)<sup>2</sup> (citing *Digital Control Inc. v. The Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006)). Harman respectfully submits that summary judgment in its favor is warranted.

**I. MIT’S ARGUMENTS ABOUT THE “LIMITED, CONTROLLED DISTRIBUTION OF JIM DAVIS’ THESIS” ARE CONTRARY TO LAW**

MIT incorrectly argues that Harman must show that Davis’ distribution of the thesis and public defense of it constitutes invalidating prior art. The question before this Court is not the invalidity question of whether Davis’ thesis was a “printed publication” or “publicly available” (*i.e.*, § 102 prior art). *See Li Second Family*, 231 F.3d at 1380. To establish MIT’s inequitable conduct, Harman need only show that MIT made a material misrepresentation with intent to deceive the PTO. *See Dippin’ Dots, Inc. v. Mosey et al.*, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (“A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” (citing *Digital Control*, 437 F.3d at 1313)). With MIT’s own admissions and record evidence, Harman meets this burden.

MIT candidly admits that the primary inventor, Jim Davis, performed a “limited, controlled distribution of [his] thesis” and that MIT withheld that information from the PTO. Opp. at 2. Still, MIT argues without any authority, that such distribution is “irrelevant to the patentability of the invention” (Opp. at 2), because “Harman must prove, by clear and

---

<sup>2</sup> Harman Exhibits (“Ex.”) 1-29 were included with Harman’s April 11, 2007 Opening Brief. Exhibits 30-46 are filed with this reply brief.

convincing evidence, that drafts of Jim Davis' thesis and Jim Davis' thesis defense predating the 'critical date' . . . were 'printed publications' that were 'publicly available . . . .'" under § 102 of the Patent Act. Opp. at 14. As discussed above, MIT's arguments are legally incorrect. MIT knows the Federal Circuit has found a reference to be § 102 art in an earlier patent case brought by MIT where MIT's inventor "orally presented" a paper and distributed copies of it "on request, without any restrictions . . . more than one year before the filing date of the . . . patents." *Mass. Inst. Tech. v. AB Fortia*, 774 F.2d 1104, 1108–1109 (Fed. Cir. 1985). MIT did the same thing with Davis' thesis here.

Similarly, MIT's argument that it was truthful, and therefore did not intend to deceive the PTO, when it stated that "the thesis did not become available to the public more than a year before the filing date of the present application," fails. Opp. at 14, 19 (emphasis removed). MIT's argument fails because the statement is false. It is undisputed that Davis did publicly defended his thesis, and did distributed copies of it to at least two people before the critical date (Opp. at 2). Moreover, Harman has presented evidence that Davis made the thesis available to others (*see* Section II. B., *infra*).

**A. MIT's Misrepresentation, That The Thesis Was Not Publicly Available Prior To The Critical Date, Was Material As A Matter Of Law.**

MIT concedes that Davis distributed his thesis before the critical date and that MIT never told the PTO about the "limited, controlled distribution of Jim Davis' thesis." Opp. at 2; HSO 31. These undisputed facts alone establish that MIT deprived the Examiner of the opportunity to decide whether those distributions barred the patent. *See Cargill Inc. v. Canabra Foods Ltd.*, 476 F.3d 1359, 1367 (Fed. Cir. 2007) (*quoting LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (any doubts as to materiality must be "resolved in favor of disclosure"))). But MIT did more than just withhold that information, MIT misrepresented the

availability of Davis' thesis in order to overcome a rejection, stating that the only way to access Davis' thesis was through the MIT library. Ex. 2 at 803. MIT's misrepresentation was material because the so-called "limited, controlled distribution" was completely independent of when the MIT library shelved Davis' thesis. HSOF 6, 8, 11; *see also Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1378 (Fed. Cir. 2006) ("undisclosed prior art was material because it was inconsistent with Agfa's misleading statements to the examiner during prosecution"). By MIT's own admission, the library was not the only way for "interested members of the relevant public [to] obtain the information [Davis thesis] if they wanted to." *See Constant v. Advanced Micro-Devices, Inc.*, 848 F. 2d 1560, 1569 (Fed. Cir. 1988).

Not only does MIT admit that actual distributions occurred, MIT also concedes that Davis "could print a copy [of his thesis] whenever he wanted and give that to anybody that he wanted to." Opp. at 2, 15, 16; MSOF; CSOF 29. MIT nevertheless contends those distributions were not material because they were (i) "limited" and only "close colleagues and [his thesis] advisors" or "actual members of Jim Davis' thesis committee or colleagues acting in an academic advisory capacity" "received drafts or a finalized version of Jim Davis' thesis;" and (ii) "controlled" because the receiving parties somehow "understood they had an obligation not to *publish* the drafts" even "without a formal confidentiality designation." Opp. at 2, 15 (emphasis added), 18; MSOF 34.

MIT's argument that "a limited dissemination to professional colleagues does not make [Davis' thesis] a 'printed publication' where professional and behavioral norms entitle a party to a reasonable expectation that the information . . . will not be copied" misses the point and is not supported by the case MIT cites. Opp. at 15-16 (citing *In re Klopfenstein*, 380 F.3d 1345, 1351 (Fed. Cir. 2004)). The *Klopfenstein* court actually wrote: "[w]here professional and behavioral

norms entitle a party to a reasonable expectation that the information displayed will not be copied, *we are more reluctant* to find something a ‘printed publication.’” *Klopfenstein*, 380 F.3d at 1351 (emphasis added). In *Klopfenstein* the court engaged “a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public” and found a slideshow to be a § 102(b) printed publication because it was displayed (not distributed or copied) to the “pertinent part of the public” who could appreciate what was novel about the invention. *Id.* at 1350 (emphasis added). If a slide show constitutes a printed publication, then so too is a limited distribution of an exact copy of the thesis paper that caused the initial rejection of the patent application.

Regardless of how MIT characterizes these admitted thesis distributions now, withholding that information from the PTO deprived the Examiner from considering whether those distributions affected patentability. After MIT’s previous experience in *AB Fortia*, there can be no legitimate dispute that Davis’ multiple distributions, as well as Davis’ undisputed offer to distribute his thesis to a University of Minnesota student (*See Harman’s Opening Brief* at 5; *Ex. 23*), each alone could have affected patentability. *See AB Fortia*, 774 F.2d at 1108–09.

Another undisputed fact is that Davis’ supposed “close colleagues and his thesis advisors” were Lynn Streeter, Phil Rittmueller and Mike Lesk.<sup>3</sup> MIT admits that Streeter was a Bell Labs’ employee when she received a copy of Davis’ thesis, yet points to no affiliation between Streeter and MIT or Davis at that time. *Opp.* at 16; *HSOF* 8. Instead, the only MIT-Streeter link in the record is Streeter’s current retention as a purported expert in this case. *See Ex. 37* at 59:6-7 (**[[REDACTED]]**)

---

<sup>3</sup> MIT claims that, in addition to Streeter and Rittmueller, Davis also distributed his thesis to Mike Lesk, a Bell Lab’s employee who also served on Davis’ thesis committee. *Opp.* at 15-16.

MIT further contradicts itself on the issue of MIT's control over the thesis distribution. According to MIT, "Lesk worked at Bell Laboratories and shared a draft with . . . Lynn Streeter." Opp. at 16; *see also* MSOF 48 (characterizing Streeter as "a professional colleague in an advisory role.") The undisputed fact that Lesk freely shared the thesis refutes MIT's unsupported contention that Streeter and Lesk were subject to any informal confidentiality obligations. Like most academic institutions, promoting academic freedom is part of MIT's mission, which encourages generating, disseminating, and preserving knowledge, not confidentiality and secrecy. *See* HSOF 13. It is, thus, not surprising that MIT did all of this, without ever imposing any confidentiality restrictions.

**B. MIT's Declarations, As A Matter of Law, Create No Issue Of Material Fact.**

More egregious is MIT's attempt to manufacture a dispute about the timing and lack of confidentiality surrounding its "limited, controlled distribution" by "submitting witness declarations that contradict their own deposition testimony," particularly since MIT counsel of record here was admonished by another Court for doing just that. *See In re Metoprolol Succinate Patent Litig.*, No. MDL NO. 1620, 2006 WL 120343, at \*20 (E.D. Mo. Jan. 17, 2006) (attached as Ex. 46) (court admonished client for "a pattern of submitting witness declarations that contradict their own deposition testimony"). As that court stated, "[a] party cannot avoid summary judgment by filing a declaration that contradicts that party's...deposition testimony." *Id.* The same treatment of MIT's declarations is warranted here. Streeter's declaration should be given no weight because it contradicts her deposition testimony and exceeds her personal knowledge, as shown in the comparison of her deposition testimony and her declaration, attached as Ex. 30. *See also* MIT Exh. 7; MSOF 49; CSOF 8. Likewise, Davis' declaration should be given no weight because it contradicts his deposition testimony, as shown in the comparison of

his deposition testimony and his declaration, attached as Ex. 31. *See also* MIT Exh. 5; MSOF 9-10, 27, 30-31, 34-35, 37-39, 48, 50; CSOF 5-6, 8, 10, 12, 29, 58.

Moreover, Rittmueller (the primary NEC liaison with MIT) did not testify that “he understood NEC’s sponsored research was confidential” as MIT now claims. Opp. at 18. In fact, Rittmueller’s sworn deposition testimony belies any such understanding:

**[[REDACTED]]**

Ex. 13 & 34 at 303:3-8, 305:22-306:5, 306:6-307:3.

MIT strains credulity even further when it candidly admits that “Phil Rittmueller . . . produced from his files a copy of Jim Davis’ thesis and a ‘Final Report’ to NEC dated July 31, 1989,” but then claims that Rittmueller “received Jim Davis’ thesis (and possibly the Final Report) after the thesis was shelved in the MIT library,” some six months after the “July 31, 1989” date on the Final Report. Opp. at 17-18 (emphasis in original). Even Rittmueller, who is **[[REDACTED]]** that he received the July 31 report with the attachments including Davis’ thesis **[[REDACTED]]** cannot remember when he received it, other than **[[REDACTED]]** July 31 and **[[REDACTED]]** Ex. 34 at 149:2-16, 151:5-10. Schmandt’s recently declared belief that “Phil did not get a copy of Jim’s thesis until after it was shelved in MIT’s library,” contradicts Rittmueller’s own recollection and, as such, cannot be used to genuinely dispute the July 31, 1989 document (Ex. 19). MIT Exh. 4 at ¶ 5.

MIT also cannot defeat summary judgment by calling the Streeter and Rittmueller copies of Davis’ thesis “drafts,” particularly since MIT does not dispute that those “drafts” match, line-for-line and word-for-word, the copy of Davis’ thesis from the MIT library. HSOF 11. There is no dispute that Streeter and Rittmueller received final copies of Davis’ thesis, not drafts. It is undisputed that they each contain exactly the same text that the Examiner initially determined was invalidating prior art (Ex. 2 at 442) and the same text that was shelved in MIT’s library.

Yet, MIT told the PTO that the thesis was not available to the public, even though MIT, Davis, and Schmandt, all knew that there was a “limited, controlled distribution of Jim Davis’ thesis” from sources other than the MIT library. Ex. 2 at 803. This “limited, controlled distribution of Jim Davis’ thesis” is directly adverse to MIT’s statements to the PTO that Davis’ thesis was not available before February 27, 1990, and makes MIT’s misrepresentations to the PTO highly material. *See Agfa*, 451 F.3d at 1380 (“undisclosed prior art was material because it was inconsistent with Agfa’s misleading statements to the examiner during prosecution”).

**C. Davis’ Public Defense Of His Thesis Was Also Material As A Matter Of Law.**

In addition to the admitted actual distributions of Davis’ thesis, it is undisputed that Davis publicly defended his thesis. MSOF 31. Also undisputed is that this, too, is something MIT chose not to disclose to the PTO. CSOF 30. Given that the Examiner expressly found “[c]laims 1-58 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Ph.D. Thesis of J.R. Davis,” a reasonable Examiner would have considered information about a public disclosure of the Davis thesis important. Ex. 2 at 442; *see Li Second Family*, 231 F.3d at 1380.

MIT’s contention that Davis’ public defense of his thesis is not material because it supposedly did not occur on May 26, 1989<sup>4</sup> (Opp. at 17) cannot defeat Harman’s motion, particularly since MIT has yet to say *when* Davis defended his thesis, and because MIT does not

---

<sup>4</sup> MIT’s claim that the thesis defense flyer is inadmissible hearsay is misplaced. MIT contends the flyer is faulty because it “was not produced by MIT,” but instead preserved by “a Kirkland and Ellis partner who, coincidentally, worked with Jim Davis years ago at MIT.” Opp. at 17. MIT’s contention has no basis in law or fact. Mr. Grove, while an undergraduate student at MIT, completed a UROP related to the Back Seat Driver under the direction of Schmandt. In his thesis, Davis credited Grove by name. Ex. 2 at 116. Mr. Grove provided the document to Harman’s counsel when he first learned of its relevance to this case, shortly after he joined Kirkland & Ellis LLP. Indeed, MIT has authenticated the thesis defense flyer in its opposition: “[t]he May 26, 1989 draft was created at a time when Jim Davis thought he might be able to graduate in June of 1989.” MSOF 39. Therefore, the document is authentic and not hearsay under Fed. R. Evid. § 801(d)(2)(A) (statement of a party opponent). As such, there is no genuine dispute as to the admissibility of the thesis defense flyer, and there is no need for Harman to call Mr. Grove at trial unless MIT continues these authenticity arguments.

deny that it happened prior to the critical date:

- “I [Davis] may have thought at one time that my thesis would be ready to defend on May 26, 1989, but in fact, it was not ready to defend until sometime later in the summer.” MIT Exh. 5 at ¶ 6.
- “Jim actually defended his thesis in late summer of 1989...” MIT Exh. 4 at ¶ 7.

The only record evidence about Davis’ thesis defense, shows that the general public was invited to a presentation that was to occur on May 26, 1989. Ex. 5. The only evidence MIT offers to contradict this document, is the self-serving, unspecific testimony of the patent’s two inventors, neither of whom remembers when Davis publicly defended his thesis, although Schmandt does recall that “Jim defended his thesis in a larger room.” MIT Exh. 4 at ¶ 7. None of MIT’s proffered evidence rises to the level of “specific facts showing that there is a genuine issue for trial,” regarding the materiality of the public thesis defense. FED. R. CIV. P. 56(e).

A reasonable Examiner would have considered important a public defense of Davis’ thesis, even if it occurred “sometime later in the summer” or “late summer of 1989,” given the close proximity to the critical date, and MIT’s representation that Davis’ thesis was not “available to the public” until February 27, 1990. Then again, had MIT disclosed this information during prosecution, MIT’s current memory lapses could have been avoided, and the Examiner would have been able to investigate in 1990. No genuine issue of material fact precludes this Court from concluding that the public defense of Davis’ thesis, which MIT withheld from the Examiner, was material.

**D. MIT Intentionally Deceived The PTO When It Knew Of, But Deliberately Did Not Disclose, The Availability Of The Davis Thesis**

MIT’s knowledge of, and conscious decision to withhold, information about the “limited, controlled distribution” and public defense of Davis’ thesis confirms its intent to deceive the PTO regarding the availability of Davis’ thesis. MIT does not dispute that it decided to withhold

this information and that it knew what it was doing when it did so. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995) (intent is “most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor.”). In light of *AB Fortia*, MIT cannot dispute that it understood the “natural consequences” of its actions. *See id.*

There is no dispute that MIT knew and withheld information about the public availability of Davis’ thesis. Harman’s SOF 26-31. There is no dispute that the information MIT withheld was uniquely known to MIT—there was no way for the PTO to uncover these facts independent of MIT’s duty to disclose them, which is why patent applicants have a duty of candor.<sup>5</sup> Even if MIT believed these were not public disclosures, MIT was not entitled to make that determination itself; rather, MIT was required to disclose the information and let the PTO decide the issue. *See Cargill*, 476 F.3d at 1367.

Further evidence of MIT’s intent to deceive flows from the undisputed facts showing that MIT’s relationship with its sponsor, NEC, was in jeopardy due to the **[[REDACTED]]** way in which MIT handled the prosecution of the ’685 patent. Ex. 6. There is no dispute that NEC voiced concerns about the prosecution of the Back Seat Driver patent. HSOF 17-20. There is no dispute that MIT took those concerns from its “unhappy customer” seriously. HSOF 20. There is no dispute that sponsorship funds, such as NEC’s, are vital to the MIT Media Lab. *See Harman’s Response to MSOF 12*. That “NEC continued to sponsor the MIT Media Lab after the Back Seat Driver project was completed” affirms just how vital NEC’s support was, and shows that MIT was able to placate NEC as a result of its inequitable conduct. MIT Exh. 4 at ¶ 9.

---

<sup>5</sup> *See Refac Intern., Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996) (“the inference [of an intent to mislead] arises [in part] from the inability of the examiner to investigate the facts.” (quoting *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993))); *eSpeed, Inc. et al. v. Brokertec USA, L.L.C.*, No. 2006-1385, 2007 WL 817665, at \* 7 (Fed. Cir. March 20, 2007) (Ex. 29) (material where it “left the examiner with the impression that the examiner did not need to conduct any further . . . investigation” (quoting *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1377 (Fed. Cir. 2000))).

There is no dispute that the issuance of the Back Seat Driver patent benefited MIT. *See* Harman's Reply to HSOF 18-20.

By withholding material information, MIT prevented the Examiner from considering it and from raising additional concerns about MIT's patent application—or worse, rejecting it, again. The only conclusion on this record is that MIT intended to deceive the PTO when it withheld material information about the availability of Davis' thesis.

## **II. MIT'S ARGUMENT THAT THE 50 USES OF "THE PATENTABLE INVENTION" WERE "IMMATERIAL" AND "CUMULATIVE" IS WRONG AS A MATTER OF LAW**

MIT goes to great lengths to argue that the undisclosed public uses were "field trials" conducted by 50 "undergraduate students" who signed some "informed consent" that impliedly "obligated [them] by ethical and academic considerations" to maintain confidentiality. Opp. at 7, 10; MSOF 42. But the record evidence MIT cites does not support that characterization and, even if it did, MIT is wrong as a matter of law.

Calling them "field trials" understates the undisputed fact that more than half of the '685 patent's claims, including the sole independent claim, were reduced to practice "at least as early as June 1989." HSOF 47, 48; Ex. 10. "[O]nce the invention is reduced to practice, there can be no experimental use." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354 (Fed. Cir. 2002). This means that it makes no difference "that the Back Seat Driver prototype could only be driven around Cambridge or Boston if Jim Davis or Chris Schmandt were in the car supervising" or whether Davis and Schmandt were observing "reactions to the spoken directions and to selecting a destination," or evaluating "how drivers would respond to spoken instructions provided by the Back Seat Driver," or gauging the "durability of cellular phone connections for data and speech transmission," or "perfecting the spoken output of the Back Seat Driver." Opp. at 7. "[A]s a matter of law, none of the subsequent uses . . . could be experimental." *New*

*Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002) (affirming invalidity due to public use).

As to the 50 people who used “the patentable invention” being merely “undergraduate students,” the undisputed evidence demonstrates otherwise. Opp. at 6–7. The document MIT cites (MIT Exh. 18) shows that, at most, 14 of the “50 subjects” were students, which hardly supports MIT’s argument that the these 50 uses “*primarily* involved undergraduate test subjects.” Opp at 7 (emphasis added).<sup>6</sup> More importantly, MIT did not present any evidence that the several General Motors’ employees or the Bell Labs’ employee or the NEC employees were “undergraduate students.” HSOF 42. Indeed, MIT fails to address these known, third-party subjects at all in its opposition.

Finally, there is no record evidence that the “informed consent” (Opp. at 10) some of the 50 subjects allegedly signed, “obligated [all 50 people] by ethical and academic considerations” (CSOF 42) to maintain confidentiality. “MIT’s rules on using students for experimental purposes,” (Opp. at 7) were completely silent as to confidentiality. *See* MIT Exh. 18. The “informed consent” that MIT claims each subject had to sign<sup>7</sup> addresses several issues, including a liability waiver and explanation of the subject’s rights and responsibilities during the drives. *See* MIT Exh. 18; HSOF 43. The document does not even mention confidentiality or secrecy, let alone impose any such obligations on the subjects. And, as Schmandt explained in 1988, “Jim Davis or Chris Schmandt were in the car supervising” for reasons unrelated to confidentiality (MIT Exh. 19):

---

<sup>6</sup> MIT claims Exh. 18 establishes that all “subjects” had to be approved by the Committee on the Use of Humans as Experimental Subjects and each subject had to sign an “informed consent” form. In applying to the Committee for approval, however, Schmandt indicates that only 14 subjects participated under the guise of this “informed consent” from the beginning of the project through December 19, 1989. MIT Exh. 18.

<sup>7</sup> MIT has not produced any signed “informed consents” in this litigation, not even for the alleged 14 “undergraduate students” who drove “the patentable invention.”

While testing the Back Seat Driver, the car will never be driven without a research team member along, for several reasons. Most important, of course, is that the whole point of doing road trials is to observe actually using the system. Secondly, any audio or video recording will be done by the observer in the car. Thirdly, the research team member will be required to operate the computer equipment and cellular telephones in the car.

Upon inspection, MIT's opposition boils down to its contention that it had no obligation to disclose any details about the 50 public uses because those uses were either immaterial or cumulative. But even the documents upon which MIT relies to support this contention show it is without merit.

**A. The Information That MIT Withheld About The 50 Public Uses Of "The Patentable Invention" Was Material.**

In arguing that the 50 public uses were not material, MIT again overstates Harman's burden. Opp. at 6-8. Not only is the invalidity issue not before the Court on this motion, MIT misstates public use law.<sup>8</sup> Whether a public use under § 102(b) or not, what matters for this motion is that the information MIT withheld about the 50 public uses of "the patentable invention" was material. The record here compels that conclusion.

MIT told the PTO about the "actual working prototype" because it knew the 50 public uses were material. Ex. 1 at 3:4. In addition, the August 1990 patent application fails to say

---

<sup>8</sup> Both *Invitrogen* and Federal Circuit precedent hold that "[a] bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting." *Invitrogen Corp. v. BioCrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). "Public use" **does not** require a use that discloses the invention to the public. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994). Instead, "any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor" constitutes public use under § 102(b). *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1119 (Fed. Cir. 1996). Put another way, the legal standard is not "whether the test subjects of Jim Davis' and Chris Schmandt's field trials might have believed they were being shown how the Back Seat Driver prototype worked, so that they could themselves publicly disclose or use the information" as MIT contends. Opp. at 9. See *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) ("The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, i.e., the place where control of the system is exercised and beneficial use of the system obtained.") Whether "elements of the 'invention' were inside the car and entirely out of view of the public" is entirely beside the point. The Back Seat Driver was used in public "in its natural or intended way," and such use is public for purposes of § 102(b). See *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (holding that a corset worn openly was in public use even though the invention was concealed within the corset); *Hall v. Macneale*, 107 U.S. 90 (1883) (holding that a safe mechanism was in public use even though the invention could not be seen without destroying the safe).

*when any of the uses occurred* (thus giving the Examiner no reason to suspect any pre-critical date uses), fails to inform the Examiner that claimed subject matter *was already reduced to practice* at the time of pre-critical date uses, fails to inform the Examiner that *50 persons other than the inventors used the system*, and incorrectly implies that the uses were not a “practical implementation” by stating that “[i]t is easy to foresee a practical implementation in the future,” thereby leading the Examiner away from the conclusion that the uses could not have been for purposes of experimentation with respect to the already reduced-to-practice subject matter. Ex. 1 at 3:7-8.

Accepting MIT’s admissions about “the patentable invention” and the June 1989 reduction to practice of the sole independent claim that eliminates, as a matter of law, any experimental use, the alleged “field trials” were public uses of the invention. *See Allen Eng’g*, 299 F.3d at 1354. Regardless, even if the 50 public uses could be experimental, the law is clear that any question of materiality must be decided in favor of disclosure. *See Cargill*, 476 F.3d at 1364.

As discussed above, there is no evidence that any of the subjects were under any obligation of confidentiality or secrecy. As such, that argument fails as a matter of law. Opp. at 8-9. In particular, MIT’s reliance on *Bernhardt* for the proposition that “confidentiality agreements were not necessary” is misplaced. Opp. at 9 (citing *Bernhardt, LLC v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1381 (Fed. Cir. 2004)). Although *Bernhardt* lacked signed confidentiality agreements, there was ample evidence demonstrating more than a mere “understanding” of confidentiality. In *Bernhardt* the patented designs were on display at a “Pre-Market” exhibition to only a “small number of industry insiders,” who went through tight security to even get into the exhibition. *Bernhardt*, 386 F.3d at 1380. Unlike here, in

*Berhnhardt* there was “no effective means for the attendees to divulge the designs they viewed,” “an industry-wide understanding that [] attendees were to hold in confidence the designs they viewed,” and “a breach of confidence could have serious consequences.” *Id.* at 1380. MIT not only has no comparable evidence, the record evidence here is inapposite. Fifty undocumented people drove the Back Seat Driver around the public streets of Boston without any confidentiality obligation. HSOF 43; CSOF 43; HSOF 41; *see also Baxter Intern., Inv. v. COBE Labs., Inc.*, 88 F.3d 1054, 1058-9 (Fed. Cir. 1996) (rejecting patentee’s argument that confidentiality should be implied when a use occurs under an ethical obligation to refrain from taking credit for the work of others, or from publishing the work of others without permission, and affirming summary judgment of invalidity under the “public use” bar of § 102(b) where use occurred within a single government laboratory where “co-workers” and “visitors” witnessed the use without a specific obligation of confidentiality)

MIT’s unsupported assertion that “[t]here is no question that the purpose of the field trials was not to offer the Back Seat Driver for sale or otherwise commercially exploit it” is not dispositive either. *Opp.* at 7; MSOF 12-13; *see Klopfenstein*, 380 F.3d at 1350 (citing commercial exploitation as one of many public use factors). The undisputed facts are that a Bell Labs’ employee, one or more NEC employees, several General Motors’ employees, and 14 “undergraduate students,” and dozens of unidentified subjects drove the Back Seat Driver. HSOF 42. At the very least, the NEC demonstrations had some commercial considerations given that NEC was a sponsor of the media lab and MIT valued its continued sponsorship. *See* MIT Exh. 4 at ¶ 9. Regardless, MIT offers no explanation of what the other subjects who comprised the 50 were doing in the Back Seat Driver.

**B. The Information That MIT Withheld About The 50 Public Uses Of “The Patentable Invention” Was Not Cumulative.**

MIT argues that “[b]ecause additional information about the field trials was at least cumulative with the five prior references . . . made of record in the ’685 patent prosecution, MIT had no legal obligation to disclose any additional information about [them] to the Patent Office Examiner.” Opp. at 13. MIT’s “five prior references” do not accurately represent what MIT knew and chose not to disclose to the PTO about the public uses. There is no dispute that none of the references discloses the *number* of public uses, the *identities* of the third-party users, the *lack of confidentiality*, the claimed subject matters embodied in the public uses, that the invention was complete with respect to those claims, or that the claimed subject matter was already reduced to practice at the time of the uses. See MIT Exh. 12, 13, 15; Ex. 2 (citing an absence of this information). As such, those references did not render cumulative the information MIT withheld. Even if it was arguably cumulative, none of the information MIT deliberately withheld was so cumulative that it absolved MIT of its obligation to disclose it. Even if the materiality of this information was questionable, MIT should have erred on the side of disclosure, just as the rules of patent office practice that governed MIT’s prosecution counseled:

[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention.

MPEP 2004 ¶ 11 (5th Ed. 1983) (attached as Ex. 44); see also *McKesson*, Ex. 45 at \*23 (“the MPEP to which [the prosecuting attorney] would have referred while the [] application was pending leaves no doubt that [the references at issue] fall squarely within the duty of candor.”)

MIT knew that telling the Examiner about the 50 public uses of “the patentable invention” occurred before the critical date, “might have resulted in the patent[] not being issued.” *Cargill*, 476 F.3d at 1365 (finding inequitable conduct where the applicant “unilaterally

withheld information that unquestionably would have been viewed as worthy of serious consideration by the PTO, and might have resulted in the patents not being issued.”) The Examiner did not “lapse[] in his duty” here as MIT contends. Opp. at 13. Instead, by representing that “it is easy to foresee a practical implementation in the future” MIT misled the Examiner into believing that no further investigation was necessary. Ex. 2 at 114; *see eSpeed*, Ex. 29 at \*7 (finding a misrepresentation to the PTO material where it “left the examiner with the impression that the examiner did not need to conduct any further . . . investigation” (quoting *Semiconductor*, 204 F.3d at 1377)). This kind of subtle deception is what gives rise to the duty of candor.

**C. MIT Intentionally Deceived The PTO When It Knew Of, But Deliberately Did Not Disclose, The 50 Public Uses Of “The Patentable Invention.”**

MIT cannot overcome Harman’s evidence of deceptive intent with the unsupported assertion that it “properly withheld cumulative information about the field trials after disclosing the fact of those trials, especially when the field trials were not relevant in the first place.” Opp. at 19; *see also* Harman’s Response to MSOF 14. Embedding the “fact of those trials” in a few references was not enough, if for no other reason, because the details of the 50 public uses may have been subject to differing interpretations. In other words, because MIT knew or should have known that the each of 50 public uses were material, MIT should have disclosed them. *See Critikon, Inc. v. Becton Dickenson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (a patentee “facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”) MIT instead chose to withhold all of the potentially invalidating details. That is deceptive intent.

### **III. CONCLUSION**

For these reasons, there is no genuine issue of material fact that MIT withheld material information and made material misrepresentations with an intent to deceive the PTO on multiple occasions, any single one of which standing alone is sufficient to establish inequitable conduct. Harman respectfully requests that this Court enter summary judgment in Harman's favor and dismiss this case in its entirety, with prejudice.

Date: June 29, 2007

Respectfully submitted,

/s/ Courtney A. Clark

Robert J. Muldoon, Jr., BBO# 359480

Courtney A. Clark, BBO# 651381

SHERIN AND LODGEN, LLP

101 Federal Street

Boston, MA 02110

William A. Streff Jr., P.C.

Michelle A.H. Francis

Craig D. Leavell

Jamal M. Edwards

Colleen M. Garlington

Joanna Belle Gunderson

KIRKLAND & ELLIS LLP

200 East Randolph Drive

Chicago, Illinois 60601

(312) 861-2000 (phone)

(312) 861-2200 (fax)

*Attorneys for Defendant*

*Harman International Industries, Incorporated*

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on June 29, 2007.

/s/ Courtney A. Clark

Courtney A. Clark

# Exhibit 41

41

# Direction Assistance

James Raymond Davis  
and  
Thomas Frank Trobaugh

December 1987

Speech Research Group Technical Memo 1  
The Media Laboratory  
Massachusetts Institute of Technology

## Abstract

Direction Assistance is an interactive program that provides spoken directions for automobile travel within the Boston area. The program has a telephone interface which uses touch tone keypad input and synthetic speech output. Routes are both short and easily followed. The directions are given in fluent English. The program has successfully directed newcomers through Boston.

This paper tells how we built Direction Assistance, with emphasis on how the available databases are and are not useful for this application. It also talks about automatic generation of route descriptions, and compares our work to that of others.

## 1 Introduction

### 1.1 Overview

Direction Assistance consists of about 11,000 lines of CommonLisp code, runs on a Symbolics Lisp Machine, and uses a Digital Equipment Corporation DecTalk synthesizer. It was written mostly during the summer of 1985 at the Thinking Machines Corporation of Cambridge, Mass. Since then, it has undergone periodic rewrites. It is running at the Media Lab, and is also installed at the Computer Museum in Boston and as part of the Age of Intelligent Machines exhibit traveling across the United States.

Direction Assistance consists of five modules. The Location Finder queries the user to obtain the origin and destination of the route. A location may be specified as a street address or as a telephone number. The Route Finder finds a simple, short route between the two points. The Describer generates high quality English text describing the route. The Narrator recites the route to the user. In addition, there is a graphical interface for maintenance.

These modules share a set of databases. The most important is the street map, which covers an eleven square mile area of Boston centered on the Charles River. A second database is an inverted phone directory, which provides a street address for a phone number.

In this paper, we discuss the databases, the Route Finder, and the Describer. The Location Finder and Narrator are described in [2].

It would be inappropriate to continue without mentioning the pioneering work of Jane Elliot and Mike Lesk[5,4]. Our work differs from theirs in several ways. Our interface uses synthetic speech and pushbutton telephones rather than a graphics terminal. We are much more concerned with generating fluent English text than they. On the other hand, we are not much concerned with route finding algorithms. Finally, Elliot and Lesk used a Yellow Pages database in addition to the white pages and street map. We will not clutter this paper with citations to Elliot and Lesk on every point where they have made contributions. They are to be assumed.



The New Yorker, April 6 1987 p 56

We next discuss the underlying databases, and then the modules which use them. The description of the databases will by necessity refer to features of the program in order to motivate the construction of the database.

## 2 Databases

### 2.1 Streets

Our street map began as a DIME (Dual Independent Map Encoding) file distributed by the United States Geological Survey[1]. A DIME file consists of a set of straight line segments, each with a name, a type, endpoints in longitude and latitude, and some additional information. Segment types include natural features (chiefly water boundaries), railroads, town and property lines as well as streets. The latter are also labeled with address numbers on both sides of the street at each endpoint; thus it is possible to estimate the coordinates for any street address by interpolation, assuming all lot sizes to be constant.

We began with an 11 square mile subset centered roughly on the Charles River. This includes portions of Boston (Charlestown, Allston, Back Bay, South End, North End), Brookline, and Cambridge (Cambridgeport and Harvard, Inman, Central and Kendall Squares). (See figure 1.) There are about 279 miles of streets in the map, which contains 6163 segments, of which 5506 correspond to streets. The total size is about 477 kilobytes.

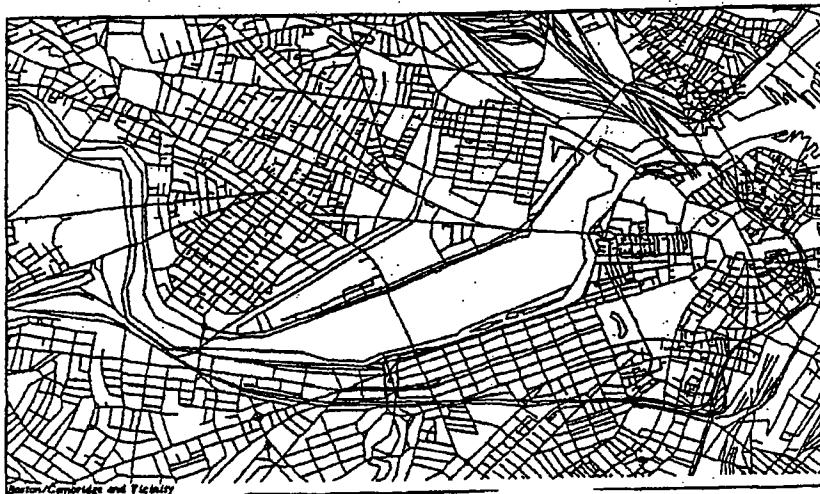


Figure 1: Street Database

The DIME file as supplied was far from suitable for our use. It contained many errors: streets were missing, mislabeled, or misconnected, and names were not spelled consistently. In some cases, more than one segment occupied the same place, and some segments were connected to themselves. We wrote a

battery of plausibility checkers to detect and remove these errors, automatically where possible.

In addition to correcting errors, we had to add new kinds of information to the database. The most important information was whether a street was one way. We also classified streets by quality, and recorded textual descriptions for some turns. We'll now describe each of these.

Segments in the DIME file are deemed to connect if they share a common endpoint. We refer to this kind of connection as *physical connectivity*. Every segment has two endpoints, and for each of these there is a list of the segments which are physically connected to that endpoint. Obviously, physical connectivity is a symmetric non-reflexive relation. Physical connectivity is not sufficient for route finding, since it may not be legal to drive from one piece of pavement to another, even though they meet, because one might be one-way, or a turn might be forbidden, or there might be a divider in the way<sup>1</sup>. To provide for the fact that one can not always drive from a segment to any other physically connected to it, we added a second kind of connection, *legal connectivity*. Two (street) segments are legally connected if one may drive from one segment to the other without breaking a law. Legal connectivity supplements, but does not replace, physical connectivity. Physically connected segments include those that can be seen in passing, and must also be retained, for they are important in forming descriptions. One cannot turn onto a railway, though the street and railroad segments are physically connected, but one may also wish to mention the crossing of the railroad as a salient detail of the tour.

Not all streets are created equal. We wanted our routes to use the widest, fastest, and most easily located streets, so we gave each street a value for goodness (super, good, average, or bad). By definition, most streets are average. The super streets are the expressways, interstate highways, and other limited access roads. Our rating of super is awarded more on the basis of being easy to find and to follow, since super roads are often crowded and slow. At the other extreme, the bad streets are those we know to be narrow or in poor repair. Our database contains only three miles of such streets. Unlike the taxi driver, we are not interested in shortcuts which use marginal streets.

The concept of "better than average" is a bit hard to define. We wanted to identify streets which were likely to be easy to find and follow. We decided that streets that were long were likely to be important, so we marked all streets longer than one half mile as "good", and then added a few more by hand if they seemed important. The resulting network is about 105 miles long, and forms a simplified skeleton covering our map. It appears in figure 2.

The third extension was to expand the street classification scheme. We added new segment types for bridges, underpasses, rotaries, and access ramps. This information is useful to both the route finder and to the describer, as we show below.

Finally, at every intersection in the map we can store additional descriptive information about each possible turn at the intersection, in the form of labelled items. Each item has a label telling what kind of information is stored, for instance an exit number or the text of a sign present at that intersection. This information is used by the Describer.

We made almost all of these corrections and augmentations ourselves from observations in the field.

---

<sup>1</sup>In this case, the turn is forbidden by physical obstacles, and not merely law or custom. But rather than engage in an epistemology of barriers, we use the same mechanism to represent this restriction.

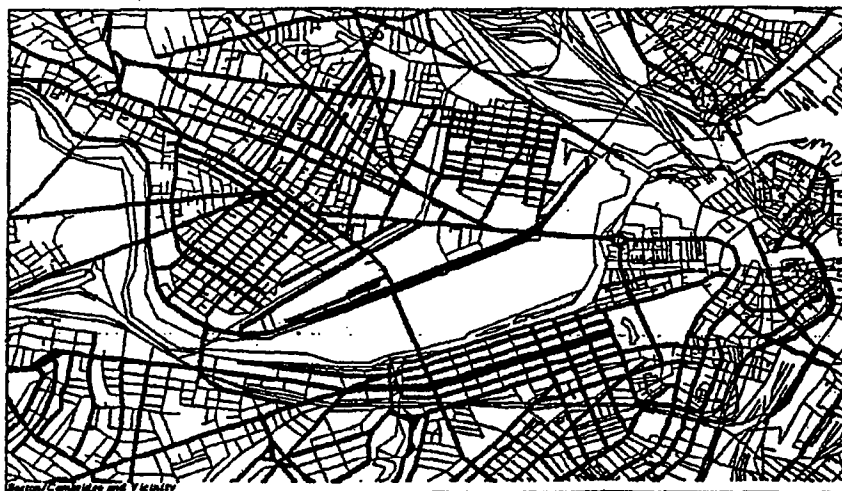


Figure 2: Network of good streets

We could not find a paper map listing all the one way and restricted turning streets of Boston, so we had to drive around looking for them. This investment in time and effort is a major cost of the system, but needs to be done only once. The graphic database editor was extremely useful, as it permitted rapid editing of the database. We commend the many designers of the Lisp Machine window system for making this easy.

## 2.2 Neighborhoods

A related database lists the neighborhoods of Boston, with their associated zip codes. We need this database because a given street might occur in several different towns. For instance, there are three distinct streets named "Washington" in our map, in Boston, Cambridge, and Somerville. Even worse, Cambridge contains two different streets named "Elm".

The Location Finder uses this database to disambiguate street names. When the user supplies a name that could designate more than one street, it is necessary to ask for further information, e.g. "Do you mean Beacon Street in Cambridge or in Boston?". To make this as easy as possible, it is best to use the names of the most general locations that still distinguish the streets<sup>2</sup>. If the street occurs in two neighborhoods of the same city, the neighborhood name is used. If the street occurs in different cities, the city name is sufficient. We determine neighborhood from the Zip code of the street. The mapping from Zip to neighborhood is imperfect, but good enough for our purposes. For the most part, the neighborhood names are those used by the local post offices. We think it is very likely that these names are also familiar to the local residents, and intelligible to visitors, but we have no evidence.

<sup>2</sup>This assumption could be tested. If people represent locales hierarchically, and if there is a preferred level of representation, it might be more difficult to determine inclusion in a too-general region.

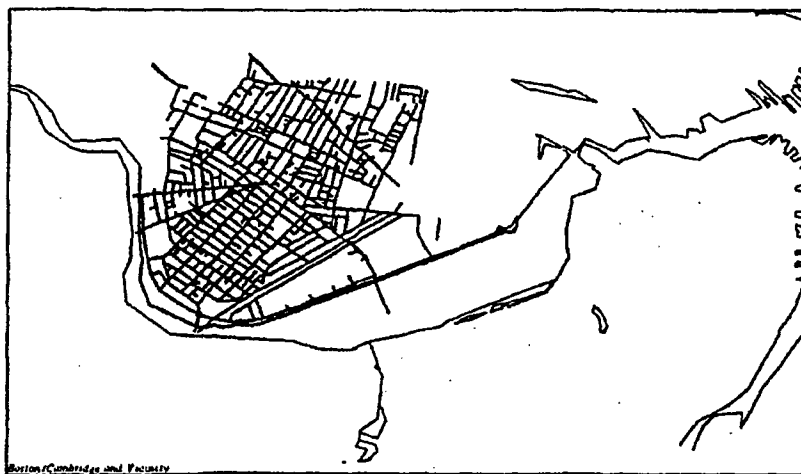


Figure 3: Central Square, 02139

### 2.3 Inverted Phonebook

The inverted telephone directory allows us to map telephone numbers to street addresses. We built this database ourselves, by inverting a "white pages" database. This required parsing the street addresses in the white pages, which was difficult for several reasons. The white pages have a great variety of spelling and abbreviation. We found, for instance, 23 variations of "Massachusetts". In addition, the format is not consistent. Sometimes listings contain professions ("atty" or "archt"), or a second phone number ("If No Answer"), or other information (e.g. "toll free", "children's phone"). We did not have the typographic information that helps separate names from locations and phone numbers. Finally, addresses are often incomplete, listing only a city, or road, or some a name which does not correspond to a street, such as a shopping center or an office park.

Even after parsing, it can be hard to determine locations from a a phone book listing. Even the best entries have at best a street, number, and city. But as we said above, streets occur in more than one place within a city. There is a rough correspondence between exchange and locale, so we can sometimes determine a unique location with this extra information. But when we can not, the Location Finder must ask the user to choose a location, as it does for street names.

Having described the databases, we now turn to the modules of Direction Assistance.

### 3 Route Finder

The Route Finder finds a route subject to three constraints. The route must be easy to follow, reasonably short, and it must be found before the user loses patience<sup>3</sup>. These constraints conflict. Rarely is there a straight line route - the shortest route may require devious shortcuts. We are biased towards simplicity, since we want our users not to get lost.

The output of the Route Finder is a *path*, an ordered list of street segments, such that the origin is on the first segment, the destination on the last, and each segment is legally connected to the next. The real time requirements of the system rule out exhaustive, breadth first search<sup>4</sup>. The current implementation uses a best first search that provides reasonably good routes in a moderate time. A sample route appears in figure 4.

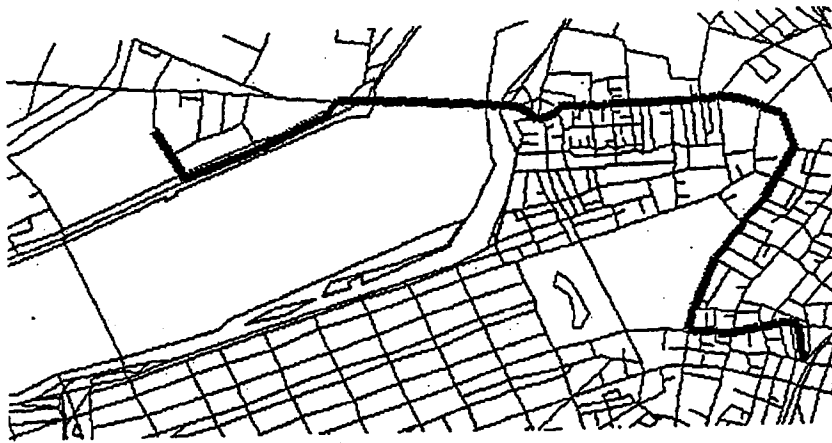


Figure 4: A sample route

Best first search is an improvement on breadth first search. Search is conducted in (simulated) parallel on a list of candidate partial paths. For each path, there is a cost which is the sum of the known cost for the current path and an estimate which is a lower bound on the cost for (as yet undetermined) remainder of the path. At each step of the search, we consider the path of least cost, and expand it by considering all segments legally connected to its terminal end. The estimation function is just the Cartesian distance, since no route can be shorter than a straight line. Figure 5 shows every segment visited by the search in finding the route shown above.

As Elliot and Lesk point out, it is not desirable to find minimum distance routes, for these have too

<sup>3</sup>A fourth constraint which we do not consider explicitly is that the route must be easy to describe. We are familiar with situations where a person asks for a route to a familiar place, but we can not describe the route because it is a "felt path": we no longer remember (or do not know) the names of the streets, only a list of subtle cues we can't describe.

<sup>4</sup>on a serial machine, anyway. An experimental version on the Connection Machine[6] works in just this way.



Figure 5: All segments touched by search

many turns. Such routes are hard to describe and hard to follow. Elliot and Lesk impose a cost of  $1/8$  mile for a right turn, and  $1/4$  mile for a left turn. We extend their system of costs in several ways. First, we consider street goodness. Travel down a "super" street is not as "expensive" as travel down an average street, and travel down a "bad" street incurs a surcharge. Second, we consider sharp right turns to be as bad as left turns, since they are harder to execute. Third, we reduce or waive turn costs in some cases. For example the turning cost is halved for a turn on to or off a one-way street, and waived altogether for a forced turn ("left turn only"). A turn onto a bridge is also free, since bridges are major landmarks, and contribute to ease of following the route. We have not studied the effect of these routes on the routes found, nor have we attempted to determine whether the routes are better where different. Such a study would require a model of driver's errors, both of understanding and of execution.

## 4 Describer

The Describer generates a set of text instructions for following the route. (An example of its output appears in figure 6.) We generate text instead of a map for two reasons. First, the system is used by telephone, which limits the output to voice. But even if our users had portable graphics terminals with modems, we would prefer text to graphics, because some people can not read maps. In a survey of map reading abilities Streeter and Vitello recommend text as a "lowest common denominator" [9].

The Describer creates a new representation of the route, instead of using the path itself. There are two reasons for this second form of representation. First, the elements of a path (segments) are too fine grained for useful textual description. Recall that a segment reaches from just one intersection to the next. This is smaller than our sense of a "street", which continues as a unity past many intersections. In addition, segments are straight lines: so a street with no intersections might be still represented as a

If your car is on the same side of the street as 20 Ames Street, turn around, and start driving. Drive all the way to the end, about one eighth of a mile. Make a left onto Memorial Drive. Drive about one eighth of a mile. After you pass Wadsworth Street on the left, take the next left. It's an easy left. Merge with Main Street. Stay on Main Street for about ninety yards, and cross the Longfellow Bridge. You'll come to a rotary. Go about half way around it, and turn onto Cambridge Street. Drive all the way to the end, about three quarters of a mile. Make a right onto Tremont Street. Drive about one half of a mile. After you pass Avery Street on the left, take the next left onto Boylston Street. Stay on Boylston Street for about one eighth of a mile. After you cross Washington Street, it becomes Essex Street. Keep going. Drive about one eighth of a mile. After you pass Ping On Street on the right, take the next right onto Edinboro Street. Number 33 is about one eighth of a mile down on your right side.

Figure 6: sample of directions

sequence of segments if it made a broad turn. We want to describe the entire stretch of a street as a single object. A second reason is that a path is just a topological structure, but natural instructions should be expressed in terms of geometry and of types of streets. Consider the difference between a "fork", a "T", and an "exit", as shown in figure 7. All have the same topology - a branch in the road. But they must be described differently. The Describer's structure is a *tour*, which is a sequence of *acts* to be taken in following the path.

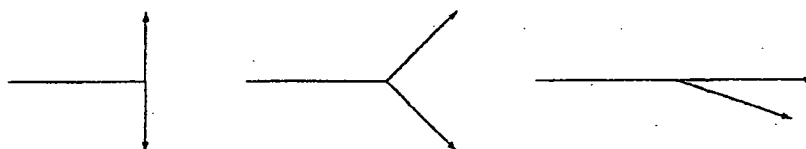


Figure 7: T, fork, and exit all have same topology

#### 4.1 Acts

Acts are things a driver does (or notices) while following a route. Figure 8 shows our taxonomy of acts.

Each of these acts must be *recognized*. The route finder works only with segments, and the Describer builds acts which describe motion from segment to segment. We now describe each of these acts, and how we recognize them. We describe the text generated for each below.

- **Boundaries**
  - **Start**
  - **Stop**
- **Straight**
  - **Name Change**
- **Turn**
  - **Enter**
  - **Exit**
  - **Merge**
  - **Fork**
  - **U Turn**
  - **Rotary**
  - **Ordinary**

Figure 8: Act Taxonomy

The first act is necessarily **START**, and the last **STOP**. They are trivial to recognize. The **NAME CHANGE** act requires the driver to notice a change in name, but nothing further. We include it only to avoid confusion. The difference between a **NAME CHANGE** and a **TURN** is that the former consists of a two streets meet within 10 degrees of straight, and where there is no other segment at the intersection with the same name as either of them. These two criterion are almost correct, but not quite right. There are streets which seem (to us) to be name changes, but have more extreme turns (at least, as represented in the map). For the present, we have caused these to be treated as name changes by changing the map, slightly altering the positions to make the turns more gentle. This would be intolerable were we using the map for, say, surveying, but is of no consequence for route description.

There are several types of **TURN** acts. The **ENTER** and **EXIT** acts refer to limited access roads. In this case, some of the travel will often be on "nameless" segments - access ramps. This shows one reason for the additional classification of street segments. We want to recognize entrances and exits, and we want to describe access ramps in different terms than other streets.

A **MERGE** and a **FORK** are similar in that they are different actions that might be taken at the same intersection, depending upon the direction one is driving. A Merge has the following characteristics:

1. Old and new streets have different names.
2. Only one street is legally possible.

3. The angle of turning is small.
4. There is at least one other street going to the destination street.
5. All streets make only small turns onto the destination.

At a FORK on the other hand, there are at least two ways to go, though all are shallow turns. Note that a "fork" onto an exit ramp is recognized as an EXIT.

There are two types of U turn known to drivers in Boston. The first kind is made in the middle of the street (within a single segment, in our representation). Our routes never include such turns. Not only are they illegal, such moves never shorten the path. The second kind of U turn is the sort one makes to reverse direction on a divided road. Typically one makes a left onto a nameless piece of road, which is often very short, and then makes a second left. This double turn is what we call a U TURN act. It is very important to recognize this act, because describing it as two successive lefts is very confusing. It is a single entity in the minds of drivers. We recognize a U TURN as a pair of turns where the intermediate segment is less than 165 yards long, the total angle is within 20 degrees of 180, and the name of the street is unchanged after the two turns.

Perhaps the most insidious feature of Boston's streets is the ROTARY. For those not familiar with the term, a rotary is a one way street in a circle. Traffic enters the rotary on roads which are (usually) tangent to the circle, moves counterclockwise around the circumference, and exits on another tangent. Rotaries are difficult to traverse because they cars enter and exit within a very short distance, without much room to maneuver. Recognition of a rotary is trivial, but only because we label all rotary segments explicitly in the street map.

An ORDINARY turn is anything not handled by one of the above cases.

## 4.2 Cues

While the Describer is collecting the acts of the tour, it also collects cues. A cue helps the driver follow the tour. We distinguish four kinds of cues. *Action* cues tell when to do an act. *Confirmatory* cues describe things that will be seen while following the route. *Warning* cues caution the driver about possible mistakes. A warning successfully heeded also serves as a confirmatory cue. *Failure* cues describe the consequences of missing an act, e.g. "If you see this, you have gone too far".

The most common action cue is just the name of the street. An instruction such as "Turn right onto Tremont Street." tells the driver what to do and when to do it. This cue may be hard to follow, since street signs may be missing. A very strong action cue is coming to the end of a road. No one is likely to forget to turn under this circumstance, since the alternative is to leave the road. We refer to this as a "forced turn" cue.

Distance traveled is also a cue, but hard to use. People have a vague sense of distance, but not an accurate one. Still, we use distance as a secondary cue, because we can compute it easily and it helps some people. We express distance in yards when less than 1/16 of a mile, and other distances in approximate

fractions of a mile because people are accustomed to seeing distances expressed this way. We do not use tenths of miles, because some people do not know how to use odometers, and because using an odometer to calculate distance requires doing mental arithmetic, which might prove distracting while driving.

We never use blocks, since a block is not a clearly defined concept. We do not know whether a block is bounded by an intersecting street, or only by streets that cross and continue. Figure 9 illustrates this. In

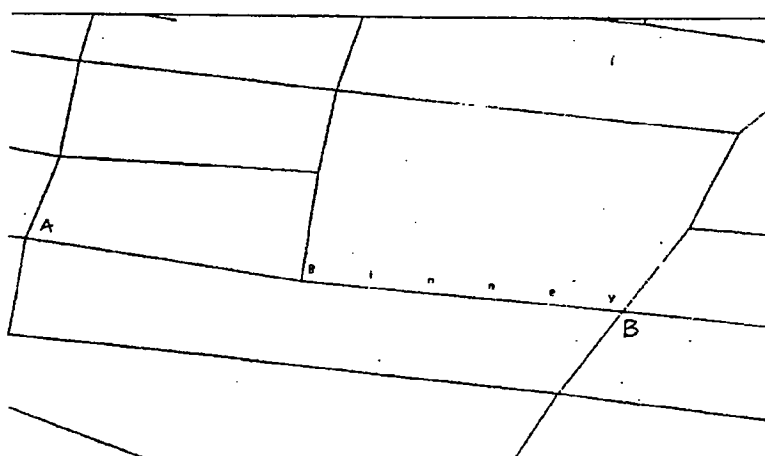


Figure 9: Is the distance between "A" and "B" one block, or two?

any event, we do not expect our drivers to be able to drive more than two or three blocks without losing count. Since we don't want to rely on distance or counting blocks, we use as a cue for an act the name of a street immediately preceding the act. This is a risky cue, since the driver who misses the cue may keep looking for it and miss the destination street as well. To make this less likely, we use only streets on the same side as the turn for a cue. This way, a driver need attend to only one side of the road while looking for street signs, so if the cue street is missed, the target street may still be seen. This same strategy is adopted in [10].

The confirmatory cues are crossing major streets or railroads, or going through an underpass. The only warning cue currently is a warning about left exits from limited access roads. We assume drivers will not take the wrong exit, but if they keep in the left lane they may be surprised by an unexpected left exit. We have not implemented failure cues.

### 4.3 Generating Text

For each act there is a corresponding routine which generates one to three sentences describing it. The routine selects appropriate cues from all those gathered. Now we'll describe some aspects of generating text.

```

(defun disc-seg-rotary (act)
  (list
    (make-sentence
      "You'll" "come" "to"
      (make-np-constituent '("rotary") :article :indefinite))
    (make-conjunction-sentence
      (make-sentence
        "Go" (rotary-angle-amount (get-info act 'rotary-angle))
        "way" "around" (make-anaphora nil "it"))
      (make-sentence
        "turn" "onto" (make-street-constituent (move-to-segment act) act))))))

(defun rotary-angle (angle)
  (selector angle <=
    (45 '("just" "a" "little"))
    (135 '("about" "a" "quarter"))
    (225 '("about" "half"))
    (315 '("about" "three" "quarters" "of" "the"))
    (360 '("almost" "all" "the"))))

```

Figure 10: Generator for rotary

Generating text for a START is tricky because it is hard to specify an initial direction. We do not use absolute directions, because most people do not know them. If we had a landmark database we might sometimes use relative direction (e.g. "towards the river"). Instead, we use the initial address, since that also determines a side of the street, and thus a direction to drive. We might have used "If your car is on the same side of the street as ... start driving the way it is facing.", but that sounded clumsy. Instead, we chose to give a negative instruction, either "If your car is on the same/opposite side of the street from ... turn around, and start driving." For one way streets we mention that the street is one way, and say "just start driving." We think (but do not know) that drivers would not have confidence in the instruction ("just start driving." ) if it did not indicate that the system knew about the one way street.

One of the simplest generators is for rotaries. It appears in figure 10. Rotaries are hard to describe and hard to follow, because there are no good references for distance around a rotary. We can not expect people to measure angular distance around the rotary, and there may not be signs. The segments of a rotaries may or may not be nameless, or there may be several names involved. The rotary itself may have a name, e.g. Leverett Circle, but this name does not appear in the database and usually does not appear on any street signs either.

Output from this generator appears in figure 6. The generator produces two sentences, the second of which is a conjunction of two sentences. The distance around the rotary is converted from an absolute angle, as measured on the map, to an approximation in English.

The instructions generated have syntactic structure only for sake of exploiting generality in text generation. Thus the function `make-np-constituent` handles agreement between the article and the noun. The function `make-sentence` ensures that capitalization and punctuation are correct. Text is sent directly to the synthesizer, and punctuation is required to achieve proper intonation. The function `make-anaphora` serves no purpose at present, but in planned future research will allow us to convey intonational features of discourse[3].

#### 4.4 Comparison

We can compare our descriptions with those generated by Streeter and colleagues[10].

Streeter's descriptions are intended to be understood and acted upon in real time, as if uttered by a navigator in the next seat. (In fact, they are recorded on a tape, and the driver pushes a button to play the next instruction.) This interface imposes a new requirement on the form of the directions. Since they are to be heard and acted on in real time, it is important to repeat essential information so that it can be remembered. In our interface, we assume people are writing down the directions before they begin to drive, so repetition is not crucial. (The user can ask the Narrator to replay an instruction if it is not understood.)

They classify turns into ordinary turns, "T" turns, complex intersections, turns in short succession, and continues. Their "T" turn is our "forced turn" cue. The difference between an ordinary turn and a "T" turn is that the latter needs no failure cue. So our treatments are similar. We do not distinguish complex intersections, though we should. The Route Finder should avoid them, and the Describer should warn about them.

Their instructions are sometimes more structured than ours. They cluster turns which occur close to each other into a single instruction block, and their "continue" is just our "name change", but is also incorporated into the following turn. We recognize the importance of providing higher levels of structure, and wish to remind the reader that Streeter and company were working by hand, not with a program, and were in a better position to form hierarchies than we.

We claim that our directions are more natural than those of Elliot and Lesk, but have no proof for this. We leave it to the reader to judge.

Are our directions clear? We know that people have been able to follow them, but we have not made any systematic test. Christopher Riesbeck wrote a program (MGMAP) which judged the clarity of directions. Our directions would not be acceptable to it, to judge from its published description. Partly this is because we talk about features the program does not know, for example rotaries, but also because his program explicitly rejects use of miles for distance as inherently unclear. We use mileage only as an approximation, as a cue for when to look for a landmark, but the weak syntactic powers of MGMAP would not notice this. Also, we use "drive all the way to end", which Riesbeck terms a "procedural operator", and did not implement. Since people accept our directions, this suggests that Riesbeck's rules are too strict, or perhaps not powerful enough.

## 5 Discussion

Products like Direction Assistance are beginning to appear in the marketplace. It is reported that ETAK, of Sunnyvale California, has a product (the Navigator) which, installed in a car, estimates the car's position by counting wheel rotation and turning angle and comparing results with a stored map. A display in the dashboard displays the local area and the position of the car. The Navigator does not supply driving directions, but surely could be made to do so.

A more similar product is DriverGuide, made by Karlin and Collins, also of Sunnyvale, which is reported to produce printed directions for travel in the Bay Area[8].

### 5.1 Better databases are required

Any serious use of Direction Assistance requires further improvements to the street map. The area covered is too small, and even the small region covered is not fully mapped. More significantly, there are additional facts that the current street database format can not represent.

Among these are time-dependent legal restrictions (e.g. "no left turn during rush hour"), restriction of height, weight, and prohibition of commercial vehicles, multiple names of streets, presence of stop lights, and landmarks. In addition, the representation of addresses is not sufficient. We have seen addresses with fractions and with letters, and there are also streets where both even and odd numbers are on the same side of the street.

A practical system must account for multiple names. When Route 93 passes through Boston, it is also Route 3, the Fitzgerald Expressway, and the Southeast Expressway. When Massachusetts Avenue turns north at Harvard Square, only the southbound lane is "really" Massachusetts Avenue. The other direction is officially Peabody Street. We do not know which name to use when naming these streets, but we should at least be able to accept all synonyms on input.

Boston, like any city, changes its configuration of streets daily. Some changes, e.g. for construction, are temporary, although they may persist for years. Others are permanent. Streets are built and removed, and sometimes they change names or directions. A practical system requires accurate and timely corrections to the database.

We could give better directions with a better database, giving, for example the location of traffic lights or landmarks such as gas stations. Elliot and Lesk were able to capture business locations from an online Yellow Pages. To be more ambitious, we might hope for a representation rich enough to capture the qualities of image and orientation described by Kevin Lynch[7]. We have no proposal for how to do this at present.

## 5.2 Applications

We initially designed Direction Assistance with tourists in mind. Boston's confusing streets often lead the visitor astray. A tourist's direction guide could be provided by the city, or as a profitable venture. But a tourist may not know the street address or phone number for the destination. In fact, there may not be one, for the destination might be a general area, such as a neighborhood or park. Tourists would probably prefer to identify locations by name. It might be difficult to add this feature without making the interface more complicated.

Direction Assistance could direct people to services. Given the caller's location and the type of service desired, Direction Assistance could select the closest, and provide a route. This service might be dedicated to a single vendor (e.g. for banking machines) or as an advertising service for many customers.

Routing delivery vehicles pose special problems. Some of the most useful routes in Boston are closed to commercial vehicles, either for legal reasons or because they have such low underpasses that even scofflaws can not get through. We could extend the street database to record such facts.

We also feel compelled to mention the implications of Direction Assistance for privacy. Should a public Direction Assistance include home telephone numbers? People may want to keep the ability to give out their home phone numbers without also revealing their addresses to callers. One can hang up on an annoying caller. A visitor may be harder to dispose of.

## Acknowledgments

A prototype version was written by Dinarte R. Morais during the winter of 1985. We are indebted to him for decoding the DIME files, the initial window system interface, and the proof of concept. We made extensive use of a database package and string matcher written by Craig Stanfill. Charles Lieserson made major improvements to the search algorithm of the Route Finder. Fletch McCellan of the PhoneBook Corporation loaned us the raw phone book database. This work would not have happened without the guidance and persistence of Brewster Kahle. This paper was much clarified by the comments of Janet Cahn, Mike Hawley, Margaret Minksy, and Chris Schmandt. We thank them all.

This work was supported at MIT by the DARPA Space and Naval Warfare Systems Command, under contract numbers N00039-89-C-0406 and N00039-86-PRDX002 and by the Nippon Telegraph and Telephone Public Corporation. Hardware support was provided by Symbolics and Digital Equipment Corporation.

This paper bears the names of two authors, for the program was joint work. But though it is written in the plural, it is the work of only one of us. I dedicate it to Tom, who did not survive to see his work described. Though too small a memorial, it is the best I can manage at this time.

## References

- [1] *Geographic Base File GBDF/DIME: 1980 Technical Documentation*. U.S. Department of Commerce, Data Users Services Division, 1980.
- [2] James R. Davis. Giving directions: a voice interface to an urban navigation program. In *Proceedings of 1986 Conference*, pages 77-84, American Voice I/O Society, Sept 1986.
- [3] James R. Davis and Julia Hirschberg. Automatic generation of prosodic support for discourse structure. In *Proceedings of the Association for Computational Linguistics*, page (submitted), 1988.
- [4] R. J. Elliot and M. E. Lesk. *Let Your Fingers Do the Driving: Maps, Yellow Pages, and Shortest Path Algorithms*. Technical Report unpublished, Bell Laboratories, 1982.
- [5] R. J. Elliot and M. E. Lesk. Route finding in street maps by computers and people. In *Proceedings of the National Conference on Artificial Intelligence*, pages 258-261, 1982.
- [6] W. Daniel Hillis. *The Connection Machine*. MIT Press, 1985.
- [7] Kevin Lynch. *The Image of the City*. MIT Press, 1960.
- [8] Ronald Rosenberg. Mapping out a new idea. *The Boston Globe*, 39, 1987. February 17.
- [9] Lynn A. Streeter and Diane Vitello. A profile of drivers' map reading abilities. *Human Factors*, 28:223-239, 1986.
- [10] Lynn A. Streeter, Diane Vitello, and Susan A. Wonsiewicz. How to tell people where to go: comparing navigational aids. *International Journal of Man/Machine Systems*, 22(5):549-562, May 1985.

# Exhibit 42

**Telling You  
Where to Go  
Thesis Proposal**

**James Raymond Davis**

**MIT Media Laboratory**

**1 January 1989**

**Submitted to the Media Arts and Science Section  
in partial fulfillment of the degree of  
Ph.D. in Media Arts and Sciences**

.....  
**Nicholas Negroponte, Thesis Advisor**

.....  
**Steve Benton, Thesis Coordinator**

.....  
**Christopher Schmandt, Reader**

.....  
**Michael Lynch, Reader  
Department of Sociology, Boston University**

**STREETER 00218**

This thesis is about helping drivers navigate through a city. This can be quite difficult. It is hard to get good instructions for getting from one place to another, and easy to get lost. A computer navigation assistant would be useful to drivers of delivery trucks, taxis, emergency vehicles; to tourists and ordinary drivers. I propose to build a computer program to give spoken driving instructions to the operator of a car in real time - that is, on a moment to moment basis. I call the system I envision the **Back Seat Driver**. This name has two connotations: first, that of an unwanted critic of one's driving skills, the second that of a helpful agent who can direct one through a locale. It is the latter sense I intend.

The next section describes earlier work on navigation systems, which I then criticise. Next I discuss in greater detail the system I intend to build, with particular emphasis on what is new and different about it. In that discussion I raise several theoretical issues which this thesis will investigate.

## Previous navigation systems

### Elliot and Lesk

The pioneering work on computer navigation is by Elliot and Lesk[3,4]. Finding a route through a street map is a special case of the general mathematical problem of searching a graph. Mathematicians and programmers have created algorithms for searching graphs, but these algorithms are not suitable for the practical problem of route finding. Partly this is because real street maps are large, but also simpler than general graphs. The general algorithms are expensive to use because they can handle any kind of graph. Elliot and Lesk got better performance by using simpler algorithms. More importantly, the general algorithms find the shortest route, but that is not the best route, if it is too complicated to remember or follow. The shortest route may be through a maze of shortcuts. People who saw such routes "recoiled in horror", so Elliot and Lesk modified their algorithm to prefer a route which was slightly longer but had fewer turns. This they accomplished by imposing a fictitious distance penalty of  $1/4$  mile for left turns and  $1/8$  mile for right turns. This change may even make routes faster to follow, since, at least for left turns, one may have to wait for traffic to clear before making the turn. Every known route finder includes functions to trade distance for simplicity.

Elliot and Lesk also were the first to implement a program to generate natural language driving instructions for the route. This is not a straightforward translation. The route as represented by the route-finding algorithm is a sequence of street segments, where a segment is a piece of a road chosen short enough that it is a straight line and no intersection occurs except at a segment endpoint. This

does not match any commonsense notion of a road. Route descriptions must be expressed in terms of motion along streets (across many segments) and turns. In their instructions, a route consists of a beginning, a sequence of turns and crossings (of rivers or railroads), and an ending. For each of these, there is a template to generate a sentence. The template has words fixed and others to be filled in according to the particulars. An example template is

Go <distance> [<intersections>] turn <direction> on <street>.

This template might produce Go 0.3 miles (2 intersections) turn left on TROY HILLS RD. Here "Go", "turn", and "on" are the fixed words, and everything else is a slot. The intersection count is optional, and only provided if relevant to the route.

A third contribution of Elliot and Lesk was to integrate the digital map with other location oriented databases, including a Yellow Pages and a personal address book. This allowed the program to find routes to addresses given a person's name, to find the closest store of a specified category, and to mention stores along the route as possible landmarks. It is not clear that this last feature was helpful, since many stores are not easy to see from the street.

## Direction Assistance

My earlier project, Direction Assistance, was directly inspired by Elliot and Lesk. A long description appears in [2]. Direction Assistance differs from the work of Elliot and Lesk in several ways. It speaks its directions instead of printing or drawing a map. The interface uses only speech and touch-tone telephone buttons, to make the program accessible from any touch tone phone, instead of requiring a computer terminal[1]. The route-finding algorithm is an A\* (best first) search algorithm[7], and the route weighting scheme is different. The weighting scheme ranks roads by a four-valued "goodness" feature and penalizes routes that use less good roads by multiplying the mileage by a constant factor. It also reduces or waives the penalty for turning under a set of circumstance having to do with predicted ease of following: for example, a turn onto a one way street incurs a lesser penalty, since it is unlikely that the driver would turn the wrong way.

The third, and most significant, difference is that Direction Assistance generates high quality English prose descriptions of the route. The prose is better because Direction Assistance does not generate text directly from the route, but instead first analyzes the route into a sequence of "acts", and then describes the sequence. An act represents something that the driver does rather than motion from one street segment to the next. There are eleven different acts, each representing a different

way of moving. The type of act to use depends upon topology (how many streets are present at an intersection, and which way traffic can flow), geometry (what angles the streets make) and what kind of streets are involved. Thus we say "bear right at the fork" rather than "turn right", but we don't say that in taking an exit from a highway we are "bearing right". An act may involve more than one segment, as for instance a "U Turn" on Memorial Drive (shown in figure 1) takes one from Memorial Drive, to Danforth, and back onto Memorial Drive, yet should not be described as two successive turns. For each act there is a specialized text generator

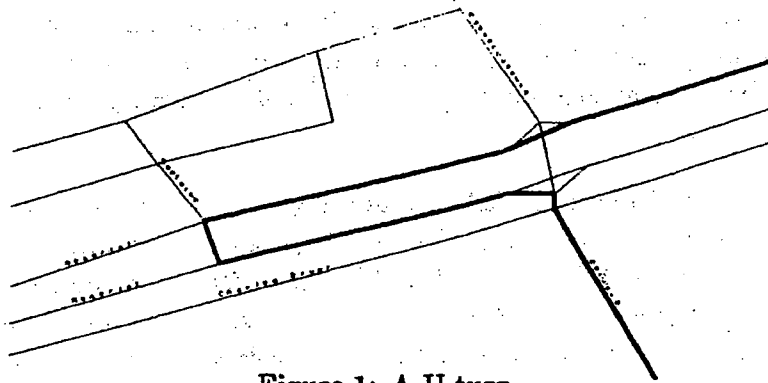


Figure 1: A U turn

to describe it, and there is a function to find an appropriate cue or landmark (e.g. a street crossed or an underpass) just before the act.

## Others

Peeder Ma describes a system which gives textual directions in [11]. His work, apparently created independently, is similar to both Elliot and Lesk's and my own work. He uses A\* search with a penalty factor to minimize the number of turns. Unlike Elliot and Lesk, he uses the same penalty for both left and right turns. His street map representation does not include one-way streets, or restrictions on turning ("no left turn") so it does not always find usable routes. His route descriptions use a taxonomy about as elaborate as that of Direction Assistance, but the text generated is more stylized.

The Hertz car rental company offers "Computerized Driving Directions" at some of its rental counters. The directions include approximate mileage and estimate travel time, but are highly schematic, even cryptic. An example appears in figure 2. It is not clear whether this system actually finds and describes routes independently, or simply prints out a pre-stored set of instructions.

The ETAK corporation has a navigation system for cars which displays the car's position on a map display on the dashboard. The ETAK system is complementary

APPROXIMATELY 16.8 MILES 0 :35 TIME  
 2.0 MI NORTH TO I-78 WEST enter LEFT  
 14.0 MI WEST TO NEW PRO/BERKELEY EXT bear RIGHT  
 DIAMOND HILL RD continue  
 0.4 MI TO MOUNTAIN AVE turn RIGHT  
 0.4 MI TO AT&T/BELL LABS on your right

Figure 2: Text of driving instructions provided by Hertz

to those described above: it does not tell you how to get anywhere, but does tell you where you are.

## Classifying navigation systems

Navigation systems can provide two kinds of services. They can tell you where you are or they can tell you what to do. I use the adjective *positional* to refer to the first kind, and *instructional* to refer to the second. A navigation system can be both positional and instructional. Navigation systems can be further distinguished by how they provide the information to your ears (verbal) or to your eyes (visual), and by whether they work in real time or in advance. The systems of Elliot and Lesk, Ma, and Hertz provide advance, written instructions. Direction Assistance gives advance spoken instructions. The ETAK system gives real time graphic positions. An ordinary map provides neither position nor instruction information. It is not a navigation system. The categories of this classification are not independent. There can be no advance positioning system, since one can not predict the future position of the car.

There are several problems with "advance directional" navigation systems. First, they do nothing to help the driver follow the route. The driver must determine for herself when to apply each instruction. Instructions like "drive half a mile, then turn left onto Maple Street" are no use if the driver is unable to measure mileage or fails to find the street sign. Indeed, in Boston many street signs are missing. In addition, the driver must keep track of which instruction is next. A second problem is that since the instructions must be specified in advance, there is no possibility of correcting if the driver does not follow the instructions, which might happen from error, or because the instructions are wrong, or simply ill-advised (as when confronting a traffic jam).

The sole existing "positional" system, the ETAK, is graphic. One can use it for navigation, if one can read a map and find one's own route. But many people have

difficulty finding and following routes on a map[13]. Even if drivers can safely read maps while driving[5], the activity is still distracting. Drivers need to see things outside the car. A navigation aid should be verbal, and leave the eyes free for driving. Drivers are more likely to arrive at their goal when given verbal instructions than when given maps; indeed, not only are verbal instructions better than a map, but adding a map to a set of verbal instructions actually hinders performance[14].

The Back Seat Driver will provide real time spoken instructions. (It will also be capable of providing position information on request.) It will have none of the drawbacks of the other systems. It will be easier to use, and thus safer to use. The next section examines the Back Seat Driver from a variety of different perspectives, showing what work I am building on and where I expect to make a new contribution.

## The planned system

The Back Seat Driver will communicate to the driver through synthetic speech. Position sensing hardware in the car will supply it with the car's position, direction, and speed several times a second. The program will find the best route to the desired destination<sup>1</sup>, then guide the user through the route, step by step, until the user reaches the destination.

There is usually more than one way to travel between two points. The Back Seat Driver will know about people's preferences for routes. One driver may prefer the fastest route, regardless of difficulty where another may want the route that makes the least demands on attention and skills. Still another driver may prefer a scenic route than passes along the river. The route finder will be able to accommodate these preferences.

The Back Seat Driver models a route as sequence of acts taken by the driver. The task of the Back Seat Driver is to get the driver to perform each act at the right time. Driving instructions must be timed to the accuracy of about one second. (The timings would be much much tighter if the Back Seat Driver had to actually turn the steering wheel. Fortunately, a human does the actual driving.) The Back Seat Driver will give driving instructions well before the act (e.g. "You'll continue on for a mile, and then make a left onto Beacon Street.") and also just before the act ("Beacon Street is the next left, get ready.") It will attempt to anticipate the driver's mistakes (e.g. "The turn is just ahead, slow down.") and, if the driver does make a mistake, it will find a new route.

---

<sup>1</sup>I ignore the question of how the driver specifies a destination. Speech recognition would probably be best, but state of the art speech recognition does not permit this even in a quiet room, and a car is very noisy. I will use some sort of keyboard, and leave this problem to someone else.

The Back Seat Driver will have other capabilities beyond navigation. It can act as a tour guide, commenting on the streets and neighborhoods traversed. People want to be oriented while traveling - it would not be pleasant to follow a route through a completely unknown area, with only the computer as guide. Kevin Lynch writes of an *imageable* city as one where the nature of places and the relations among them are easily grasped[10]. The Back Seat Driver can help make the city more imageable by telling the driver how the paths and nodes of the city fit together.

The Back Seat Driver can also relay messages from home or office. It is already possible for people to get telephone calls while driving, but it might be more convenient to have a smart answering machine like the Phone Slave[12] screening calls. After all, we can't always safely answer the phone while driving. These messages might also include the driver's own reminders for shopping. In this case, the Back Seat Driver can keep an eye out for vendors lying along the route. It might spontaneously mention a place where needed goods could be obtained, or the driver might ask for a route to the closest provider.

## Interactivity and Goals

The Back Seat Driver is a truly *interactive* system, by which I mean that both parties are active all the time. Most "interactive" computer systems are better called *reactive* - the machine and the human take turns. While the human is typing, the computer does nothing, and there is little the human can do while the machine is working, except to interrupt a calculation gone awry. Interaction is inherent in the application, because the concept of "turn taking" does not apply, since the driver's actions are continuous. There is never a time when the driver is not driving.

The Back Seat Driver pursues many goals at once. Its main goal is to get the driver to some location. This is a goal whose satisfaction requires many utterances over an extended time. Other goals include delivering messages and educating the driver about the city. These goals can not all be met at once, so it must choose which to pursue at any given moment. To make this choice properly it requires a model of action. It takes action to achieve a goal, and actions take a finite amount of time. The only kind of action Back Seat Driver can take is to talk. Since it can only say one word at a time, it must choose its words carefully. At any moment when the Back Seat Driver is not already speaking, it can either begin saying something, or it can wait. This decision must be made again and again, at each passing moment. A wrong decision can not be undone. Words once spoken can not be made unsaid, though the program can stop talking at any time; more seriously, there is nothing to be done if the program decides that it should have begun speaking two seconds previously<sup>2</sup>. Since the driver's actions are unpredictable, the program

<sup>2</sup>Save perhaps to speak faster, a possibility I will not consider further.

must improvise.

The problem, then is to allocate a resource (speaking time) to goals so that the most important goals get as much time as they need, while lesser goals get any left over. To do this, at any time, each goal must provide three pieces of information about itself:

- Is it ready to speak – that is, is there something that could be said right now which would help achieve the goal.
- If so, what is the maximum amount of time the speech would require, or
- If not, what is the minimum time until the goal will be ready to speak.

The latter two measures will be estimates, since they depend in part on the driver's future actions. Given these estimates, and a preassigned priority for each goal, the program will at each moment authorize a goal to speak, by examining each, in order of decreasing priority. The goal of highest priority that is ready to speak will be allowed to do so, unless there is some other goal of greater importance which, though not currently ready to speak, can be expected to begin speaking in less time than the the lesser goal will use in speaking. Thus the Back Seat Driver will not be constantly interrupting itself, uselessly starting a narrative it can't finish. Nevertheless, interruption will sometimes happen anyway, since the driver may make a mistake at any time, and correcting the mistake may require immediate action.

The Back Seat Driver should anticipate the driver's future actions, rather than simply react to the driver's current action. Unfortunately, the only information it has about the driver is the the position and speed of the car. The program can not tell what the driver is looking at, or see the driver's facial expression. Given limited information, it can make only limited guesses of the driver's intentions. Speed can be a useful clue. If the program knows that the driver is approaching a turn, yet is driving quickly, the program can infer that either the driver is unaware of the turn, or is unconcerned with safety. In either case, it is appropriate to tell the driver to slow down<sup>3</sup>. The Back Seat Driver should understand the dynamics of car motion sufficiently well that it can tell whether it is possible for the driver to slow down enough to make the turn in the time remaining. If not, the program may as well not bother, but instead begin replanning for the inevitable mistake.

---

<sup>3</sup>Comments about the driver's speed make the Back Seat Driver act more like the "nag" that the term usually connotes.

## Discourse structure

The Back Seat Driver requires a model of discourse structure. A discourse is what you get when you have more than one utterance and more than one party to a conversation. This is clearly the case with Back Seat Driver, as there are two parties to the conversation, the Back Seat Driver speaking and the driver listening and reacting, and there are also multiple utterances. Discourse has structure: it has parts, and there are relations among the parts. In this section I briefly introduce discourse structure and show how it will be applied by the Back Seat Driver

I plan to use the discourse structure proposed by Grosz and Sidner[6]. They analyze discourse structure as consisting of three parts: linguistic structure, intentional structure, and attentional structure. Linguistic structure is the actual utterance, as speech or text. The elements of the discourse can be divided into a set of discourse segments which are hierarchically related – that is one segment may contain other segments. They do not specify the size of a discourse segment, but it may be as small as a phrase, though usually it is a sentence or two.

Intentional structure concerns the purposes of the discourse and its component parts. A discourse has a single discourse purpose (DP) which the speaker intends that the hearer recognize. It may have other purposes as well, but these are not treated by discourse structure. Intentional structure assigns each discourse segment a single discourse segment purpose (DSP). There may be a relation between the DSPs of any two segments. Segment A is said to *dominate* segment B when B's DSP contributes in some way to A's – that is, when B is a subgoal of A. Segment A *satisfaction-precedes* B when A's DSP must be achieved before B's.

Attentional structure concerns how objects and concepts used in the discourse become salient (brought into focus in the conversation), are used, and finally replaced. Their model of attentional structure is a stack of focus spaces, where more recently mentioned objects are higher on the stack, and thus more accessible. Not everything on the stack is accessible. When an interruption occurs, focus spaces below the stack are temporarily inaccessible.

Discourse structure is dynamic - as the conversation goes on, more and more of it is constructed. Items are pushed and popped from the attentional (focus) space, and as discourse segments are heard their DSPs are linked. At the end of a conversation, the focus space will be empty, and the intentional structure fully constructed. We can think of intentional structure as monotonically increasing - things are added, but never erased, except perhaps for corrections to mistakes. But the attentional structure is a stack - at the end of a conversation it should be empty.

Discourse structure is required for generating or comprehending fluent language. The presence of a concept in an accessible focus space is what allows one to use a

pronoun or reduced descriptor to refer to it. You might say

- (1) I heard George's first speech.
- (2) He's as twisted as Ronald.

Here, the object George is first mentioned in (1), and pushed on to the attentional stack. Then it can be referred to by the pronoun "he", or we could say

- (3) The slippery devil was in perfect form.

Only through a mechanism like attentional structure can you tell that this sentence attributes "slippery devilhood" to George.

Intentional structure reflects the relations between concepts being related. It is as much a part of the information being transmitted as the words themselves. For instance, when a discourse contains an example, the point of it is altogether lost if the reader fails to notice the relation between the purpose of the subgoal and that of the main goal. We have a great many "cue phrases" in English which indicate intentional structure explicitly, such as "first", or "e.g.", or even "such as".) Discourse that lacks cue phrases is harder to comprehend, therefore they should be included. However, generating key phrases without a principled representation of discourse structure is quite difficult.

The Back Seat Driver must keep track of what it is doing and what it has said (or done, since it can only do by saying) so that it can repeat an utterance upon request. Sometimes the driver will not understand the Back Seat Driver's speech, since cars and streets are noisy. When asked to repeat, the system must know not merely the last sequence of words, but also the meaning and purpose of those words. Yes, sometimes a literal repeat will be enough, but in other cases the simple passing of time requires a change in wording. Consider the case when the driver is approaching a turn, and the system says "Take the second left onto Broadway." To repeat this instruction word for word after crossing an intersection is to mislead the driver. A discourse structure is required to properly handle repeat requests.

The work proposed here will contribute to understanding of discourse structure by making principled implementation of the theories. No text generator to date has used discourse structure to motivate pronouns, reduced descriptors, or cue phrases. The Back Seat Driver will also push the limits of the theory because it operates in an environment where interruptions can occur (when the driver makes a mistake). This will ensure that the model of interruption processing described in the literature is at least workable, if not provably correct.

# **Exhibit 42**

## **Part II**

## Text generation

A problem left unsolved by Direction Assistance is how to talk about two actions that are done in rapid succession. In ordinary speech when we make two turns in quick succession we may say "Take a left and then an immediate right." or we might call it a "jog". This latter term suggests that the two actions have been merged into a single act. Direction Assistance had a partial solution to this problem in its understanding of a U Turn (two quick turns, both in the same direction, such that one travels in the opposite direction on a same named street.) A more general solution is required.

Back Seat Driver will have to describe acts in more than one way. Direction Assistance describes every act just once, in a future, imperative tense, but Back Seat Driver will describe actions in future tense, present tense, and past tense (when describing mistakes). Descriptions of an act should depend upon context - a turn in the (far) future is just "a left" but when it gets closer it becomes "the next left". In between, it may be appropriate to identify the turn by mentioning nearby streets or landmarks, but at the time of the turn, it will probably be better to just say "now".

The text generated by the Back Seat Driver will also have several other small improvements over that of the Direction Assistant. These changes require better understanding of how to talk about roads and routes. As an example, the route Direction Assistance finds from Memorial Drive (eastbound) onto the Harvard Bridge includes a short section of Massachusetts Avenue. (See figure 1.) Even though this segment is only a few yards long, Direction Assistance dutifully includes it in the route description. What is needed here is a sense of when a street's name is significant and when it should be elided.

## The Image of the City

### Understanding the route

The Back Seat Driver should help drivers to understand the route it gives. This goal will make the system more pleasant to use, and will facilitate following the route, because a driver who understands the route and the city will use that knowledge to help interpret the commands Back Seat Driver gives. For example, a driver following a route that crosses the Longfellow Bridge and who knows that Main Street leads to the bridge knows about how long she'll be traveling before her next instruction, and she'll be attentive to cues at the right time, instead of having to

constantly be on the lookout.

Understanding the route has at least two aspects. A simple aspect is to be oriented with respect to the route, to know how far one has come and how much is left to go. Such information is easily provided. The Back Seat Driver knows the length of the route and the elapsed mileage, and can tell the driver on request.

A second aspect is that the route should fit into a larger model of the city. This means that the Back Seat Driver itself must have a model of the city and should speak of the route in terms that relate it to the city. There are several opportunities to do this. At the beginning of the route, the driver might hear an overview of the route, naming the major paths followed and neighborhoods crossed. During the route, locations could be described not just as street address but in larger units of neighborhoods and districts. The system might say not, "You're at 900 Mass Ave." but rather "We are now half way between Central and Harvard Squares." Orienting information can be included in instructions, or it might come between instructions, as a passing comment.

Benjamin Kuipers presents a formalization model of people's ability to learn to navigate[9,8]. In his model there are three stages of spatial knowledge:

- Sensorimotor Procedures: knowledge expressed as conditional procedures: "When you see this, do that"
- Topological Relations: containment, connection, and order
- Metrical Relations: distance, direction

Sensorimotor knowledge is the first to be acquired. Here a route is a sequence of cues and things to do. This knowledge is sufficient to follow a route, but does not support reasoning about the route. You can not reverse the route, because each cue leads only to the next, in the familiar order, and not the preceding. You may not even be able to give the route to someone else, as each cue may be recalled only in the context of the one just previous. This accounts for the familiar "I can take you there, but I can't tell you how." Back Seat Driver's instructions are sensorimotor instructions - they have to be, to be executed. We can expect that drivers can at least memorize routes at this level if they follow them several times<sup>4</sup>.

---

<sup>4</sup>I do have a concern that people who depend completely on the system for decisions about which way to turn may never acquire this knowledge, since they will not use their own judgments. In my experience, I learn a route much faster when I'm the driver than when I'm a passenger. Partly this must be because the task of driving forces me to pay more attention to where I am, but also there must be an effect from trying to remember a previous route, or trying to interpret instructions or a map. It would be a pity if the Back Seat Driver actually impaired learning.

People gradually acquire topological and metrical knowledge, mostly from their own experience, but they can also use other sources of knowledge. People learn metrical relations partly by seeing maps, so it is possible that they can learn topological relations by being told. This is the justification for including orienting information in Back Seat Driver.

## Representing city knowledge

Back Seat Driver must represent knowledge about the city. In the terminology of Kevin Lynch [10], there are five components to a city's image: paths, districts, edges, nodes, and landmarks. A path is a channel for travel. A district is an area with some recognizable quality. A district has extent in two dimensions, and some boundaries, which may be sharp or vague. To Lynch, "recognizable quality" means that you can tell which district you are in just by looking around. An edge is a linear feature that is not useful for travel. Often, edges form the boundaries for districts. A node is either a junction of paths or a concentration of some quality. Landmarks designate a point as special in some way.

The same object may be classified in different ways by different people. The Charles River is an edge to the driver. To the boater, it is a path or even a district. As scale increases, a district becomes a node, and as it decreases, a node can be a district.

Some of these features are more essential for navigation than others. Clearly, paths are the most important feature. Knowledge about a path includes:

- Its name. A path might have more than one name. The Fitzgerald Expressway in downtown Boston is also Route 93 and Route 3 and the Central Artery. Only one of these names will be used for output, but the system should recognize any of them on input - and it should be prepared to warn the driver to expect to see or hear the other names.
- Where it goes. Paths link nodes. The nodes that a path connects are the most powerful means of placing the path. Nodes and landmarks along a path are the beginnings of the topological knowledge of the city that a driver must acquire.
- Its continuations, or, equivalently, its name changes. A single path might have different names in different places, or you might think of it as two separate paths that meet. Storrow Drive in Boston connects directly with Soldiers Field Road. This is best thought of as one path with two names. Cambridge Street in Brighton continues straight across the river into Central Square, but changes its name to River Street after it crosses the river. Is this two paths or one? It probably does not matter, as long as one makes a consistent

choice. Continuity is harder when the path forks. Lynch writes of how the continuity of Storrow Drive on the east is confused between Nashua Street and the Central Artery. Neither one is the clear successor. Sometimes the continuity can be so strong that the successor loses its identity. I always hear the Nonseignor O'Brien Highway in Cambridge called the McGrath Highway, which is its official name only in Somerville.

- Its spelling. Some names have spellings that are hard to predict from the pronunciation. If the system tells a driver to look for "Worcester" street, the driver might be looking for something like "Worster" unless otherwise informed. This problem is not limited to paths, of course, but this is the place it is going to come up the most.

## Landmarks

Next in importance are landmarks, which serve as cues to tell the driver when to make a particular act. Landmarks are difficult for the program to use because it has no eyes. It is unable to tell whether a landmark is visible at any given moment. Even a large building like the Hancock building is not everywhere visible. This means that the program can never use landmarks to specify direction ("Drive towards the State House."), but only to make the current location more memorable. Mentioning the State House as one drives past it makes an "anchor" for one end of Beacon Street.

The program should only use landmarks that it can be sure are visible. The landmark need not be visible when first mentioned - it may be mentioned as a thing to expect in the route overview - but it must be visible at some time. This means that the program should use only landmarks that are immediately adjacent to the street. The program can be sure that the Charles River is visible from Storrow Drive, but not from Beacon Street. In addition, the program must distinguish day and night, since some landmarks may be hard to see at night.

Lynch also speaks of "local landmarks" - features that are unique only in the context of a portion of a route, not throughout the city. Natural spoken directions often mention features like signs, traffic lights, ordinary buildings, and other cars. The Back Seat Driver will use some of them as well. It will use street sign names implicitly, simply by naming a street. It is not always possible for a driver to read a street sign, indeed, it may be missing, but it is still good to mention the name of the street. Even if it does not help the driver to find the street, the driver wants to know what street she is on. There is no easy way to identify a path except with a name, so names are essential.

The Back Seat Driver will also use traffic lights. These come up often in ordinary

directions, and are easy to spot. Presumably the driver is already watching out for traffic lights out of desire to avoid traffic accidents and tickets, if for no other reason.

## **districts and nodes**

There are some unsolved issues about the meaning of "district" and "node" in the Boston/Cambridge area: what to do with "squares" and how to represent "neighborhoods". Here I discuss these issues.

The Back Seat Driver will know about the "squares" of the city. There are several dozens of squares in the Boston area. (Here I'm referring to the squares people know about, not the ceremonial "squares" named by the city. In Cambridge, at the intersection of Mount Auburn, Putnam, and Massachusetts Avenue is a tiny island of concrete which bears a sign identifying it as "Sullivan Square". But this is not the "Sullivan Square" that people know, which is in Charlestown. There must be hundreds of these squares, but I do not think any one uses them for navigation.) Very few squares are even remotely square. For the most part, each square has a unique name. But some do not. There is one "Central Square" in East Boston and another in Cambridge.

One issue is to know what constitutes a square. When can one be said to be "at" or "in" a square? In some cases, the squares have a well defined intersection. In other cases, the square extends for several blocks. A second issue is whether the term "square" denotes the intersection (a node) or the surrounding area. A "Harvard Square" address can be a half a mile from Massachusetts Avenue.

Also at issue is the meaning of the term "neighborhood". Lynch says that districts are "always identifiable from the inside" (p. 47) but many neighborhoods are not so identifiable. Unlike districts in Boston, there is nothing in the architecture to distinguish the Inman Square neighborhood from Cambridgeport. If you don't know where you are, you won't be able to tell from looking, unless you see a street sign. It may be that most of Cambridge is one "district", in which case a smaller term is needed. In some cases it might be possible to name a neighborhood for a node, as in Inman Square, but there is no defining node for Cambridgeport. It may be that the requirement for internal identification is too strong, and must be discarded.

## **Thesis Plan**

My procedure for doing this work is empirical and iterative.

The first step is to study natural direction-giving. I will record people giving driving directions. This will be an uncontrolled study - I'll simply offer to drive people to locations they select, and record whatever instructions they give. I already have an intuition about what kinds of instructions are best to give, from my previous work with Direction Assistance. This study will add to those impressions. From this study, I'll collect a list of the forms of instructions given and the types of objects and concepts used in instructions. If I happen to make mistakes while driving, I'll study how my subjects correct me.

The second step is an iterative step. I will write the Back Seat Driver and test it. I will record the sessions, and identify places where the instructions are ambiguous, misleading, or utterly wrong, and modify the program to eliminate them. After each test, I'll learn about what works and what does not.

## implementation and resources

The program will be written in Common Lisp on a Lisp Machine. The Lisp Machine will communicate with the driver through two cellular phones. One phone will carry voice from the computer to the driver, and a second will carry data back from the car to the computer. For Back Seat Driver to be practical, it would have to use a computer small enough to fit into a car. But this is not our concern at present. Using cellular phones presents some practical difficulties: the phone system makes the speech harder to understand, and data communications between the car and the computer are unreliable. These problems will make Back Seat Driver less reliable than it should be, but hopefully not so bad as to be untestable.

The program will be written in Lisp on a Symbolics Lisp Machine already owned by the Lab. There are several items required for this research - in particular, a car - but also position-sensing hardware, cellular phones, and modems. All of these will be paid for by a grant from the sponsor of this research (Nippon Electric Corporation Home Electronics Division) or will be loaned by the sponsor.

## Acknowledgments

The author wishes to express his gratitude for the generous sponsorship of NEC Home Electronics, which makes this research possible.

## References

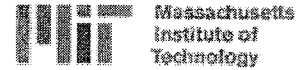
- [1] James R. Davis. *A voice interface to a Direction giving program*. Technical Report 2, MIT Media Laboratory Speech Group, Apr 1988. replaces the paper in the 1986 AVIOS proceedings titled Giving Directions: A voice interface to an urban navigation program.
- [2] James R. Davis and Thomas F. Trobaugh. *Direction Assistance*. Technical Report 1, MIT Media Laboratory Speech Group, Dec 1987.
- [3] R. J. Elliot and M. E. Lesk. *Let Your Fingers Do the Driving: Maps, Yellow Pages, and Shortest Path Algorithms*. Technical Report unpublished, Bell Laboratories, 1982.
- [4] R. J. Elliot and M. E. Lesk. Route finding in street maps by computers and people. In *Proceedings of the National Conference on Artificial Intelligence*, pages 258-261, 1982.
- [5] Walter W. Wierwille et al. Strategic use of visual resources by the driver while navigating with an in-car navigation display system. In *Proceedings Society of Automotive Engineers*, pages 2.661-2.675. paper number 885180.
- [6] Barbara J. Grosz and Candace L. Sidner. Attention, intentions, and the structure of discourse. *Computational Linguistics*, 12(3):175-204, 1986.
- [7] P. E. Hart, N. J. Nilsson, and B. Raphael. A formal basis for the heuristic determination of minimum cost paths. *IEEE Transactions on SSC*, 4:100-107, 1968.
- [8] Benjamin J. Kuipers. Modelling human knowledge of routes: partial knowledge and individual variation. In *Proceedings of the National Conference on Artificial Intelligence*, pages 216-219, 1983.
- [9] Benjamin J. Kuipers. *Representing Knowledge of Large-Scale Space*. PhD thesis, MIT, July 1977. Issued as Technical Report 418.
- [10] Kevin Lynch. *The Image of the City*. MIT Press, 1960.
- [11] Peeder Ma. An algorithm to generate verbal instructions for vehicle navigation using a geographic database. *The East Lakes Geographer*, 22:44-60, 1987.
- [12] C. Schmandt and B. Arons. A conversational telephone messaging system. *IEEE Trans. on Consumer Electr.*, CE-30(3):xxi-xxiv, 1984.
- [13] Lynn A. Streeter and Diane Vitello. A profile of drivers' map reading abilities. *Human Factors*, 28:223-239, 1986.

- [14] Lynn A. Streeter, Diane Vitello, and Susan A. Wonsiewicz. How to tell people where to go: comparing navigational aids. *International Journal of Man/Machine Systems*, 22(5):549-562, May 1985.

# Exhibit 43

2007

## MIT FACTS



## FINANCIAL DATA

## Year-end Statistics, Fiscal Year 2006 (in millions)

## Value of Plant and Invested Assets

Book value of educational plant	\$1,687.8
Market value of endowed funds	\$8,368.1
Book value of total investments	\$7,288.7
Market value of total investments	\$9,500.2

## Cash Gifts to MIT

Individuals	\$114.3
Corporations	\$40.2
Foundations	\$86.5
Other	\$0.8
<b>Total</b>	<b>\$241.8</b>

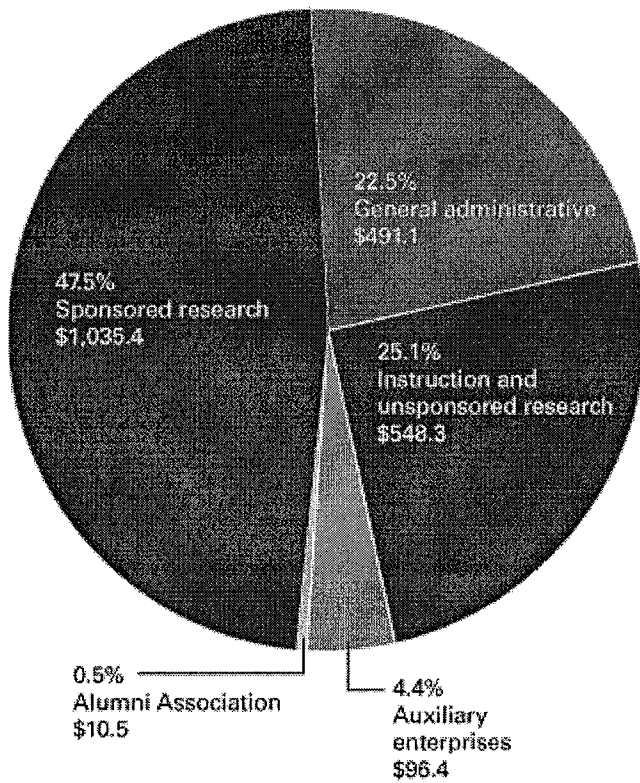
## Cash Gift Designations

Faculty chairs	\$12.2
Scholarships and other undergraduate aid	\$23.0
Undergraduate education and student life	\$4.6
Graduate fellowships	\$20.1
Research and education programs	\$133.6
Construction and renovations	\$27.2
Unrestricted	\$19.8
Undesignated	\$1.3
<b>Total</b>	<b>\$241.8</b>

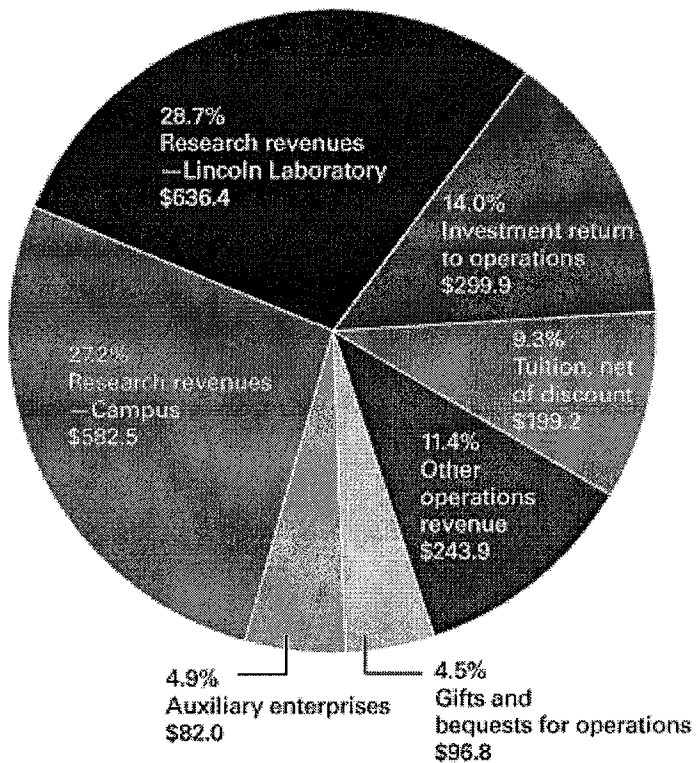
## Fiscal Year 2006

## Operating Expenditures (in millions)

Total: \$2,181.7 million



Fiscal Year 2006  
Operating Revenues (in millions)  
Total: \$2,140.7 million

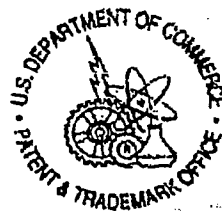




# Exhibit 44

# Manual of PATENT EXAMINING PROCEDURE

Original Fifth Edition, August 1983  
Latest Revision October 1989



U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Rev. 13, Nov. 1989

## DUTY OF DISCLOSURE; REJECTING AND STRIKING OF APPLICATIONS

2004

## BY REEXAMINATION

Where any person, including patentee, has prior art patents and/or printed publications which said person desires to have the Patent and Trademark Office consider after a patent has issued, such person may file a Request for Reexamination of the patent (see 37 CFR 1.510 and §§ 2209-2220).

**2004 Aids to Compliance With Duty of Disclosure [R-3]**

While it is not appropriate to attempt to set forth procedures by which attorneys, agents, and other individuals may ensure compliance with the duty of disclosure, the items listed below are offered as examples of possible procedures which could help avoid problems with the duty of disclosure. Though compliance with these procedures may not be required, they are presented as helpful suggestions for avoiding duty of disclosure problems.

1. Many attorneys, both corporate and private, are using letters and questionnaires for applicants and others involved with the filing and prosecution of the application and checklists for themselves and applicants to ensure compliance with the duty of disclosure. The letter generally explains the duty of disclosure and what it means to the inventor and assignee. The questionnaire asks the inventor and assignee questions about

- the origin of the invention and its point of departure from what was previously known and in the prior art,
- possible public uses and sales,
- prior publication, knowledge, patents, foreign patents, etc.

The checklist is used by the attorney to ensure that the applicant has been informed of the duty of disclosure and that the attorney has inquired of and cited material prior art.

The use of these types of aids would appear to be most helpful, though not required, in identifying prior art and may well help the attorney and the client avoid or more easily explain a potentially embarrassing and harmful "fraud" allegation.

2. It is desirable to ask questions about inventorship. Who is the proper inventor? Are there disputes or possible disputes about inventorship? If there are questions, call them to the attention of the Patent and Trademark Office.

3. It is desirable to ask questions of the inventor about the disclosure of the best mode. Make sure that the best mode is described. The disclosure of the best mode may be raised in litigation. See for example, Carlson "The Best Mode Disclosure Requirement in Patent Practice," Vol. 60, Journal of the Patent Office Society, page 171 (1978).

4. It is desirable for an attorney or agent to make certain that the inventor, especially a foreign inventor, recognizes his or her responsibilities in signing the oath or declaration. Note that 37 CFR 1.69 requires that,

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language

that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

Note § 602.06 for a more detailed discussion.

5. It is desirable for an attorney or agent to carefully evaluate and explain to the applicant and others involved the scope of the claims, particularly the broadest claims. Ask specific questions about possible prior art which might be material in reference to the broadest claim or claims. There is some tendency to mistakenly evaluate prior art in the light of the gist of what is regarded as the invention or narrower interpretations of the claims, rather than measuring the art against the broadest claim with all of its reasonable interpretations. It is desirable to pick out the broadest claim or claims and measure the materiality of prior art against a reasonably broad interpretation of these claims.

6. It may be useful to evaluate the materiality of prior art or other information from the viewpoint whether it is the closest prior art or other information. This will tend to put the prior art or other information in better perspective. However, § 1.56 may still require the submission of prior art or other information which is not as close as that of the record.

7. Care should be taken to see that prior art or other information cited in a specification or in an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized. It is particularly important for an attorney or agent to review, before filing, an application which was prepared by someone else, e.g., a foreign application. It is also important that an attorney or agent make sure that foreign clients, including foreign applicants, attorneys, and agents understand the requirements of the duty of disclosure, and that the U.S. attorney or agent review any information disclosure statements or citations to ensure that compliance with § 1.56 is present. See *Gemveto Jewelry Company, Inc. v. Lambert Bros., Inc.*, 216 USPQ 976 (S.D. New York 1982) wherein a patent was held invalid or unenforceable because patentee's foreign counsel did not disclose to patentee's United States counsel or to the Office prior art cited by the Dutch Patent Office in connection with the patentee's corresponding Dutch application. The Court stated, at 216 USPQ 985,

Foreign patent attorneys representing applicants for U.S. patents through local correspondent firms surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavorable to patentability and claiming ignorance of United States disclosure requirements.

8. Care should be taken to see that inaccurate statements or inaccurate experiments are not introduced into the specification, either inadvertently or intentionally. For example, stating that an experiment "was run" or "was conducted" when in fact the experiment was not run or conducted is a misrepresentation of the facts. No results should be represented as actual

results unless they have actually been achieved. Paper examples should not be described using the past tense. See §§ 608.01(p) item D and 707.07(l). Also, misrepresentations can occur when experiments which were run or conducted are inaccurately reported in the specification, e.g. an experiment is changed by leaving out one or more ingredients. See *Steierman v. Connelly*, 192 USPQ 433 (PTO Bd. of Pat. Int. 1975); 192 USPQ 446 (PTO Bd. of Pat. Int. 1976).

9. Do not rely upon the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be "material to the examination" of the application the examiner is considering. It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. See *Armour & Co. v. Swift & Co.*, 175 USPQ 70, 79 (7th Cir. 1972) ¶; *Kangaroos U.S.A., Inc. v. Calder, Inc.*, 222 USPQ 703, 708, 713-714 (S.D.N.Y. 1984).

While vacating the summary judgment and remanding for trial in *Kangaroos*, the Court, 228 USPQ 32 (Fed. Cir. 1985), stated at page 35 that a "lapse on the part of the examiner does not excuse applicant."

10. When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant."

11. It may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention. ¶Note *Hycor Corp. v. The Schleier Co.*, 740 F.2d 1529, 222 USPQ 553, 557-559 (Fed. Cir. 1984) ¶.

12. Submit information promptly. An applicant, attorney or agent who is aware of prior art or other information and its significance should submit same early in prosecution, e.g., before the first action by the examiner, and not wait until after allowance. ¶Potentially material information discovered late in the prosecution should be immediately submitted. That the issue fee has been paid is no reason or excuse for failing to submit information. See *Blumwood Liquid Products, Inc. v. Singleton Packing Corp.*, 170 USPQ 398 (M.D. Fla., Tampa Div. 1971) ¶.

13. It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most

significance. Note *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.* 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), affirmed, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), certiorari denied 414 U.S. 874 (1974).

14. Watch out for continuation-in-part applications where intervening material information or documents may exist; particularly watch out for foreign patents and publications related to the parent application and dated more than one year before the filing date of the CIP. These and other intervening documents may be material information: In *re Ruschetta and Jenny*, 118 USPQ 101, 104 (C.C.P.A. 1958); In *re von Lagenhoven*, 458 F.2d 132, 173 USPQ 426 (C.C.P.A. 1972); *Chromalloy American Corp. v. Alloy Surfaces Co., Inc.*, 339 F. Supp. 859, 173 USPQ 295 (D. Del. 1972).

15. Watch out for information that might be deemed to be prior art under Section 102(f) and (g).

Section 102(f) of Title 35 United States Code may be combined with Section 103; see *Corning Glass Works v. Schuyler*, 169 USPQ 193 (D.D.C. 1971), aff'd in *Corning Glass Works v. Brenner*, 175 USPQ 516, (D.C. Cir. 1975) where the District Court adopted defendant's post trial memorandum on 102(f) and 103; *Halliburton v. Dow Chemical*, 182 USPQ 178, 186 (N.D.Okla. 1974); *Dale Electronics v. R.C.L. Electronics*, 180 USPQ 225 (1st Cir. 1973) and, *Ex parte Andresen*, 212 USPQ 100 (Bd. App. 1981).

Note also that prior invention under § 102(g), may be combined with Section 103, such as in *In re Bass*, 474 F.2d 1276, 177 USPQ 178 (C.C.P.A. 1973).

¶Note 35 U.S.C. 103, second paragraph as amended by Public Law 98-622 disqualifies section 102(f)/103 or section 102(g)/103 prior art which was, at the time the second invention was made, owned by or subject to an obligation of assignment to, the person who owned the first invention: see 1050 O.G. 316.¶

16. Watch out for information picked up by the inventors and others at conventions, plant visits, in-house reviews, etc.; see, for example, *Dale Electronics, Inc. v. R.C.L. Electronics, Inc.*, 180 USPQ 225, 228 (1st Cir. 1973).

17. Make sure that all of the individuals who are subject to the duty of disclosure, such as spelled out in § 1.56 are informed of and fulfill their duty.

18. Finally, if information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

## 2005 Alterations or Partly Filling in Applications After Execution [R-3]

Applications which have not been prepared and executed in accordance with the requirements of Title

# Exhibit 45

Westlaw.

--- F.3d ---

Page 1

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

McKesson Information Solutions, Inc. v. Bridge Medical, Inc.

C.A.Fed. (Cal.), 2007.

Only the Westlaw citation is currently available.

United States Court of Appeals, Federal Circuit.  
McKESSON INFORMATION SOLUTIONS, INC.,  
Plaintiff-Appellant,

v.

BRIDGE MEDICAL, INC., Defendant-Appellee.

No. 2006-1517.

May 18, 2007.

**Background:** Patentee sued competitor for infringement of patent related to patient identification system. The United States District Court for the Eastern District of California, Frank C. Damrell, Jr., J., 2006 WL 1652518, dismissed action, finding patent unenforceable due to inequitable conduct. Patentee appealed.

**Holdings:** The Court of Appeals, Clevenger, Senior Circuit Judge, held that:

- (1) prior art that applicant failed to disclose was not merely cumulative to prior art which was before examiner;
- (2) overwhelming circumstantial evidence, coupled with lack of any credible explanation for nondisclosure of prior art, supported finding that patentee had deceptive intent;
- (3) prior rejection of three-node communication claim would have been considered important by any reasonable examiner reviewing application;
- (4) patentee intended to deceive Patent and Trademark Office (PTO) by not disclosing to examiner adverse decisions by another examiner in a closely-related application;
- (5) allowance of claims to a three-node communication system was material to application and should have been disclosed to examiner; and
- (6) district court's holding patent unenforceable was

not abuse of discretion.

Affirmed.

Newman, Circuit Judge, filed a dissenting opinion.

#### [1] Patents 291 ↪97

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings

Therein in General. Most Cited Cases

A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the Patent and Trademark Office (PTO) during prosecution. 37 C.F.R. § 1.56(a).

#### [2] Patents 291 ↪97

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings

Therein in General. Most Cited Cases

The materiality of information withheld during prosecution may be judged by the "reasonable examiner" standard, in determining whether a patent is rendered unenforceable for inequitable conduct; that is, materiality embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent. 37 C.F.R. § 1.56(a).

#### [3] Patents 291 ↪97

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings

Therein in General. Most Cited Cases

For purposes of determining whether a patent is rendered unenforceable for inequitable conduct, information concealed from the Patent and Trademark Office (PTO) may be material even though it would not invalidate the patent. 37 C.F.R. § 1.56(a).

--- F.3d ----

Page 2

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

**[4] Patents 291 ¶97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

## 291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

A withheld otherwise material piece of information is not material, for purposes of determining whether a patent is rendered unenforceable for inequitable conduct, if it is merely cumulative to that information considered by the patent examiner. 37 C.F.R. § 1.56(a).

**[5] Patents 291 ¶97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

## 291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

The intent element of the offense of inequitable conduct, which renders patent unenforceable, is in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred; however, inequitable conduct requires not intent to withhold, but rather intent to deceive. 37 C.F.R. § 1.56(a).

**[6] Patents 291 ¶97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

## 291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

In determining whether a patent is rendered unenforceable for inequitable conduct, intent to deceive cannot be inferred simply from the decision to withhold information, where the reasons given for the withholding are plausible. 37 C.F.R. § 1.56(a).

**[7] Patents 291 ¶97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

## 291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

A finding that particular conduct amounts to gross negligence does not of itself justify an inference of intent to deceive, for purposes of determining whether a patent is rendered unenforceable for inequitable

conduct; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive. 37 C.F.R. § 1.56(a).

**[8] Patents 291 ¶97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

## 291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

The party asserting inequitable conduct as defense to enforcement of a patent must prove a threshold level of materiality and intent by clear and convincing evidence; the court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other. 37 C.F.R. § 1.56(a).

**[9] Patents 291 ¶324.54**

## 291 Patents

## 291XII Infringement

## 291XII(C) Suits in Equity

## 291k324 Appeal

## 291k324.54 k. Presumptions and Discretion of Lower Court. Most Cited Cases

**Patents 291 ¶324.55(2)**

## 291 Patents

## 291XII Infringement

## 291XII(C) Suits in Equity

## 291k324 Appeal

## 291k324.55 Questions of Fact, Verdicts, and Findings

## 291k324.55(2) k. Clearly Erroneous Findings. Most Cited Cases

When, after a trial, the court has made factual findings as to materiality and deceptive intent, those factual findings are reviewed for clear error, and the decision of the ultimate issue of whether a patent is rendered unenforceable for inequitable conduct is reviewed for abuse of discretion. 37 C.F.R. § 1.56(a).

**[10] Patents 291 ¶97**

## 291 Patents

--- F.3d ----

Page 3

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

**291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

For purposes of determining whether applicant's failure to disclose prior art was inequitable conduct that rendered patent related to patient identification system unenforceable, prior art that applicant failed to disclose was not merely cumulative to prior art which was before examiner, as three-node communication system described in undisclosed art was material quite apart from anything analogous to the disclosed programmable unique identifier limitation. 37 C.F.R. § 1.56(a).

**[11] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Prior art which was before examiner did not render undisclosed prior art cumulative, for purposes of determining whether applicant's failure to disclose prior art was inequitable conduct that rendered patent related to patient identification system unenforceable; description of preferred embodiment in undisclosed prior art spanned over 11 columns and provided a highly technical discussion of the implementation of the three-node communication system with unique addressing, whereas same description in disclosed art was just under two columns and provided only cursory implementation details. 37 C.F.R. § 1.56(a).

**[12] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Prior art disclosing patent's points of novelty, including three-node communication and a unique address limitation, was noncumulative of disclosed prior art, which did not disclose anything analogous to the programmable unique identifier limitation, for purposes of determining whether failure to disclose prior art was inequitable conduct that rendered patent unenforceable. 37 C.F.R. § 1.56(a).

**[13] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Existence of differences between prior art and claims in application related to patient identification system did not, standing alone, render prior art immaterial, for purposes of determining whether failure to disclose prior art was inequitable conduct that rendered patent unenforceable. 37 C.F.R. § 1.56(a).

**[14] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Simply because examiner reviewing co-pending application cited prior art for its unique addressing feature did not release applicant's attorney from the relevance of prior art's other teachings, for purposes of making disclosure to examiner reviewing application that became patent related to patient identification system; examiner's citation to prior art put attorney on notice of the content of the whole document.

**[15] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Duty of applicant's attorney to disclose material information to Patent and Trademark Office (PTO) extended well beyond date attorney had a telephonic interview with examiner reviewing co-pending application to discuss examiner's discovery of a previously-undisclosed prior art reference, as duty of candor extended throughout patent's entire prosecution history.

**[16] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon**

291k97 k. Patent Office and Proceedings  
Therein in General. Most Cited Cases

Cancellation of claim, which incorporated both three-

--- F.3d ----

Page 4

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

node communication and a unique address limitation, by applicant's attorney, subsequent to citation to prior art disclosing those two of patent's points of novelty by examiner reviewing co-pending application supported inference of intent to deceive, as required to render patent unenforceable for inequitable conduct. 37 C.F.R. § 1.56(a).

#### [17] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Overwhelming circumstantial evidence, coupled with lack of any credible explanation for nondisclosure of prior art disclosing two of patent's points of novelty, supported finding that patentee had deceptive intent when it failed to disclose prior art to examiner during prosecution of applications leading to patent related to patient identification system. 37 C.F.R. § 1.56(a).

#### [18] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
The "reasonable examiner" standard for determining whether a patent is rendered unenforceable for inequitable conduct is satisfied in the rejected-claims setting if the rejected claims are substantially similar to the claims at issue. 37 C.F.R. § 1.56(a).

#### [19] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
A showing of substantial similarity is sufficient to prove materiality, for purposes of determining whether a patent is rendered unenforceable for inequitable conduct; it does not necessarily follow, however, that a showing of substantial similarity is necessary to prove materiality. 37 C.F.R. § 1.56(a).

#### [20] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

To the extent there is a difference among "in some respects identical," "substantially similar," and substantial similarity "in content and scope," that difference is inconsequential, for purposes of determining whether a patent is rendered unenforceable for inequitable conduct, so long as the evidence clearly and convincingly proves materiality in one of the accepted ways. 37 C.F.R. § 1.56(a).

#### [21] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

As rejected claims in co-pending applications unquestionably disclosed three-node communication, the existence of which was crucial to applicant's patentability argument, prior rejection of three-node communication would have been considered important by any reasonable examiner reviewing application reciting three-node communication as part of patient identification system, for purposes of determining whether applicant's failure to disclose rejections was inequitable conduct that rendered patent unenforceable. 37 C.F.R. § 1.56(a).

#### [22] Patents 291 ¶97

##### 291 Patents

###### 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

Applicant's cancellation of claims in patent application in the face of examiner's rejection of those same claims in co-pending application, whether it was characterized as "acquiescence" or "legitimate and acceptable practice," was evidence of materiality, for purposes of determining whether applicant's failure to disclose rejections was inequitable conduct that rendered patent related to patient identification system unenforceable. 37 C.F.R. § 1.56(a).

#### [23] Patents 291 ¶97

--- F.3d ----

Page 5

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Possibility of one small piece of evidence being cumulative was insufficient to undermine legitimacy of district court's otherwise error-free finding of materiality of alleged inequitable conduct, in applicant's failure to disclose prior rejection of claims in co-pending application related to patient identification system. 37 C.F.R. § 1.56(a).

**[24] Patents 291 ↪97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Comparison of the rejected claims in co-pending application to claims in patent application before examiner revealed that both sets of claims related to use of three-node communication and a unique address in the context of bar code reading and, thus, applicant's intent to deceive could be inferred from his assertion that claims were exempt from disclosure on grounds that they were distinct.

**[25] Patents 291 ↪97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Material rejections in co-pending applications fell squarely within applicant's duty of candor, notwithstanding claim of applicant's attorney that he showed good faith by making two separate disclosures of existence of closely-related application to examiner in the course of patent prosecution.

**[26] Patents 291 ↪97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Applicant intended to deceive Patent and Trademark Office (PTO) by not disclosing to examiner adverse decisions by another examiner in a closely-related ap-

plication for patient identification system, for purposes of determining whether patent was unenforceable for inequitable conduct; although applicant disclosed closely-related application in context of prior art cited in that application, applicant failed to mention the adverse decisions and made statements to examiner inconsistent with other examiner's decisions, indicating nothing in prior art disclosed three-node communication. 37 C.F.R. § 1.56(a).

**[27] Patents 291 ↪97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
For purposes of determining whether applicant's failure to notify examiner of allowance of prior patent claims was inequitable conduct that rendered patent related to patient identification system unenforceable, allowance of claims to a three-node communication system was material to patent application and should have been disclosed to examiner; allowance of three-node system of patent claims gave rise to a conceivable double patenting rejection, particularly in light of another examiner's conclusion during examination of a related application that addition of prior art's unique address limitation to another prior art's three-node system was obvious. 37 C.F.R. § 1.56(a).

**[28] Patents 291 ↪97**

## 291 Patents

## 291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases  
Allowance of claims in prior, related patent application was not cumulative by virtue of possibility that examiner, having heard prior application months earlier, remembered allowing claims when he heard subsequent application and then realized the materiality of such allowance to claims in subsequent application, for purposes of determining whether applicant's failure to notify examiner of allowance of prior patent claims was inequitable conduct that rendered patent related to patient identification system unenforceable. 37 C.F.R. § 1.56(a).

--- F.3d ----

Page 6

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

**[29] Patents 291 ↪97****291 Patents****291IV Applications and Proceedings Thereon****291k97 k. Patent Office and Proceedings****Therein in General. Most Cited Cases**

In light of its finding of three instances of inequitable conduct in patent application process, district court's holding patent related to patient identification system unenforceable was not abuse of discretion. 37 C.F.R. § 1.56(a).

**Patents 291 ↪328(2)****291 Patents****291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents****291k328 Patents Enumerated****291k328(2) k. Original Utility. Most Cited****Cases****Patents 291 ↪328(2)****291 Patents****291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents****291k328 Patents Enumerated****291k328(2) k. Original Utility. Most Cited****Cases**

4,180,204, 4,456,793, 4,569,421, 4,588,881, 4,593,155, 4,628,193. Cited as Prior Art.

4,835,372, 4,850,009, 4,857,716. Cited.

Daniel Johnson, Jr., Morgan Lewis & Bockius LLP, of San Francisco, California, argued for plaintiff-appellant. With him on the brief was Mark K. Dickson, Winston & Strawn LLP, of San Francisco, California. Of counsel on the brief was Marcus T. Hall.

Jose L. Pati o, Morrison & Foerster LLP, of San Diego, California, argued for defendant-appellee. With him on the brief were Eric M. Acker and Katherine L. Parker.

Before NEWMAN, Circuit Judge, CLEVINGER, Senior Circuit Judge, and BRYSON, Circuit Judge.

Opinion for the court filed by Circuit Judge CLEVINGER. Dissenting opinion filed by Circuit Judge

NEWMAN.CLEVINGER, Senior Circuit Judge.

\*1 Plaintiff McKesson Information Solutions, Inc. ("McKesson") appeals the final decision of the United States District Court for the Eastern District of California dismissing McKesson's infringement suit against defendant Bridge Medical, Inc. ("Bridge") after the court found the only patent at issue, U.S. Patent No. 4,857,716 ("the 716 patent"), unenforceable due to inequitable conduct.

As set forth in considerable detail below, this case involves McKesson's nondisclosure of three items of information during prosecution of the 716 patent in a setting where the applicant had co-pending applications. The district court found each of the three nondisclosures individually and collectively material to prosecution of the application that led to the 716 patent. With regard to deceptive intent regarding each nondisclosure, the district court found circumstantial evidence strongly supports an inference of deceptive intent. After assessing all the facts, the district court held that McKesson failed to provide a credible explanation for the material nondisclosures. As the district court noted, this was not a case of mistake or negligence-the prosecuting attorney testified that he would make all the same nondisclosure decisions again if prosecuting the same applications today.

The district court's thorough written opinion documents the court's correct understanding and application of the relevant precedent. The issues of materiality and intent are fact-driven. With regard to the issue of intent, the law recognizes that deceptive intent is virtually never shown or disproved by direct evidence. Instead, the ultimate fact finding on the issue depends on assessment of all the inferences, favorable and unfavorable, that can be drawn from pertinent evidence. To prevail on appeal, McKesson must demonstrate that the district court's findings of fact are clearly erroneous. After careful review of the record, we conclude that McKesson has not met its burden, and we therefore affirm.

I

A

The 716 patent provides "a patient identification sys-

--- F.3d ---

Page 7

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

tem for relating items with patients and ensuring that an identified item corresponds to an identified patient.” 716 patent, at [57]. This is accomplished first by providing a set of bar codes associated with a given patient such that one bar code from the set is physically attached to the patient and the other bar codes from the set are physically attached to, for example, the patient’s medications; and second by providing a portable handheld bar code reader (or patient terminal) wirelessly connected to a base station unit (typically located in the patient’s room) that communicates via modem with a system computer capable of “processing and storing patient data.” *Id.* col.30 l.23-col.31 l.17. Thus, among the handheld patient terminal, the base station, and the system computer, the 716 patent teaches a “three node approach to communications.” J.A. at 366. Moreover, because the handheld patient terminals are portable, it is desirable to prevent one such terminal from wirelessly communicating with a base station in, say, an adjacent room. The base stations of the 716 patent therefore include “a programmable unique identifier” that “only allow[s] communication with a portable handheld patient terminal ... having a corresponding program identifier.” 716 patent col.31 ll.2-7.

\*2 The only independent claim of the 716 patent incorporates both of these features-*i.e.*, three-node communications and a programmable unique identifier-as limitations. Claim 1 thus provides:

1. A patient identification and verification system comprising:

- (a) programmed *system computer means* for processing and storing patient data;
- (b) input means operatively interconnected to the programmed system computer means for input of data to the programmed system computer means;
- (c) output means operatively interconnected to the programmed system computer means for output of data from the programmed system computer means;
- (d) first bar code identifier means adapted for attachment to a patient for identification of the patient, the bar code identifier means including a patient unique code;
- (e) a plurality of second bar code identifier means for identifying patient care related items, such as medication, etc.;

(f) the input means and output means including:

- (i) microprocessor controlled *portable handheld patient terminal means* having bar code reader means for scanning the first bar code identifier means to identify the patient and for scanning the second bar code identifier means for relating various items to a specific patient, the portable handheld patient terminal means further including keyboard means for data entry and display means for display of information, the portable handheld patient terminal means including electromagnetic wave transceiver means including means for transmission of patient and item data as an electromagnetic wave which is representative of the first and second bar code identifier means scanned by the bar code reader means and including means for receipt of data as an electromagnetic wave;
- (ii) microprocessor controlled *base station means* including electromagnetic wave transceiver means for receipt of and transmission of the patient and item data as an electromagnetic wave to the electromagnetic wave transceiver means of the portable handheld patient terminal means, the base station means being interconnected to the programmed system computer means at least in part by electrical lines for receipt and transmission of the patient and item data on the electrical lines to the programmed system computer means, *the base station means includes a programmable unique identifier, the base station means including means for only allowing communication with a portable handheld patient [sic] terminal means having a corresponding program identifier, the patient system including means for programming the portable handheld patient terminal means with the corresponding identifier* [“programmable unique identifier” limitation]; and
- (iii) the programmed system computer means including program means for verifying the patient and item data properly correspond and transmitting an alarm signal if improper correspondence noted.

*Id.* col.30 l.23-col.31 l.17 (emphasis added).

\*3 On October 6, 1987, claim 1 was submitted in substantially this form-except that the “programmable unique identifier” limitation was separated as a limitation in dependent claim 6-as part of parent Application No. 06/862,278 (“the 278 application”) (subsequently abandoned) in response to an

--- F.3d ---

Page 8

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

April 6, 1987, rejection by Examiner David Trafton of the United States Patent and Trademark Office ("PTO"). Accompanying this submission were the remarks of prosecuting attorney Michael Schumann: None of the references *either singularly or in combination* teach or suggest the claimed invention. In addition to numerous other differences, *none of the references teach the three node approach to communications as provided in the claimed invention*. In the present invention, the first node of communication is a main or central computer which may have its own terminals for entry/display of information. The second node of communication are [sic] the base stations which are wired to the main computer. The base stations are preferably located in the various patient rooms and other suitable locations. The third node of communication in the present invention is the portable handheld patient terminal which cooperates with the base stations to provide for wireless transmission of data between the base station and the patient terminal. This approach provides a system which allows for maximum portability of the patient terminals and yet allows access to the main computer in an inexpensive manner by use of the base stations which provide wired communication to the main computer. Many of the references such as Koenig do disclose the use of wireless transmission which has long been in use, and many of the systems do disclose the use of bar code readers to scan bar codes to see if they correspond. However, none of the references disclose the real time, interactive three node communication system of the present invention as claimed.

J.A. at 366-67 (emphasis added).

In a December 8, 1987, office action, Examiner Trafton maintained his rejection of amended claim 1, albeit based upon a different combination of prior art references patents to Blum and Pejas. However, Examiner Trafton also explained that dependent claim 6 would be allowable if rewritten in independent form. J.A. at 371. Schumann accepted this offer on June 8, 1988, by abandoning the 278 application and filing a continuation application (Application No. 07/205,527) with the only independent claim rewritten in the manner suggested by Examiner Trafton. The claims in their current form were allowed on February 27, 1989, and the 716 patent issued on Au-

gust 15, 1989.

## B

During this same time period, Schumann was simultaneously prosecuting another application-Application No. 06/862,149 ("the 149 application")-before another PTO examiner, Robert Lev. The invention of this simultaneous application was similar to the invention of the 716 patent-so similar, in fact, that Schumann initially disclosed the same body of prior art with both applications. J.A. at 2400. The first submitted version of the 149 application included application claims 15 and 16, which together teach three-node communication:

\*4 15. A portable handheld terminal, including:

(a) a *portable handheld terminal*, including:

- (i) a housing having first and second spaced apart, opposing major surfaces extending longitudinally of the housing between first and second end portions;
- (ii) keyboard means disposed on the first surface for entering data;
- (iii) display means disposed on the first surface for displaying data;
- (iv) optical sensor means disposed in the housing for sensing bar code indicia;
- (v) RF transceiver means contained in the housing for transmitting and receiving RF signals;
- (vi) control means contained in the housing and operatively interconnected to the keyboard means, display means, optical sensor means, and RF transceiver means for controlling operation of the portable handheld terminal; and
- (vii) power supply means for powering the portable handheld terminal; and

(b) *base station means* including RF transceiver means for communication with the portable handheld terminal.

16. A system in accordance with claim 15, wherein the base station means includes:

- (a) programmed microprocessor and memory means for controlling communication between the portable handheld terminal and a *central computer system* electrically wired to the base station means;
- (b) power supply means for powering the base station means;
- (c) charger assembly means for charging the power supply means of the portable handheld terminal;

--- F.3d ----

Page 9

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

(d) data over voice (DOV) means for communication with the central computer by telephone wires using data over voice techniques; and

(e) RF transceiver means for wireless communication with the portable handheld terminal.

See J.A. at 645-46 (emphasis added).

In a February 26, 1987, office action, Examiner Lev rejected these claims as obvious over a combination of prior art references including the patents to Blum and Pejas. J.A. at 636. Although both of these prior art references were in front of Examiner Trafton prior to his April 6, 1987, rejection of the three-node communication system of the 278 application, see J.A. at 347, 355, Examiner Trafton did not cite the combination of Blum and Pejas in that rejection, see J.A. at 354. And, although Schumann disclosed the existence of the co-pending 149 application to Examiner Trafton on or about August 12, 1986, J.A. at 339, Schumann did not bring Examiner Lev's rejection of application claims 15 and 16 to Examiner Trafton's attention.

Schumann responded on August 26, 1987, to Examiner Lev's rejection by narrowing claim 15 to encompass only "real time data communication." See J.A. at 649. Schumann also added new application claims 19 through 24. Of those, claims 19 and 21 through 23 are the most relevant:

19. *A portable terminal*, comprising:

(a) a handheld housing;

(b) keyboard means disposed on the housing for entry of data, said keyboard means including separate numeric and special function key means for user input to the terminal;

\*5 (c) display means disposed on the housing for display of data;

(d) optical sensor means interconnected to the housing for sensing bar code indicia on an object;

(e) electromagnetic transceiver means in the housing for transmitting and receiving electromagnetic signals representing the exchange of data between the portable handheld terminal and a remote location while the portable handheld terminal is in use;

(f) control means contained in the housing operatively interconnected to the keyboard means, display means, optical sensor means, and electromagnetic

transceiver means for controlling operation of the portable handheld terminal; and

(g) power supply means for powering the portable handheld terminal.

*Id.* at 646-47 (emphasis added). 21. A method of receiving and transmitting patient information to a central computer location at a location remote from the central computer system, comprising the steps:

(a) sensing patient related information contained in bar code indicia by use of an optical scanner of a handheld terminal, the terminal including a keyboard for entry of additional patient related information;

(b) electromagnetically transmitting from the handheld terminal to a base station patient related information;

(c) transmitting patient related information from the base station to the central computer location by use of data over voice techniques;

(d) receiving at the base station patient related information from the central computer location by use of data over voice techniques; and

(e) electromagnetically receiving at the handheld terminal patient related information from the base station.

22. A method in accordance with claim 21, wherein the step of transmitting patient related information to the base station from the handheld terminal includes transmission of a unique address recognizable by a base station programmed to accept patient related information containing the unique address.

23. A method in accordance with claim 22, further including the step of programming with the base station, the portable handheld terminal to transmit the unique address.

*Id.* at 647-48 (emphasis added). Thus, claim 19 teaches two-node communication, claim 21 teaches three-node communication, claim 22 teaches the addition of a "unique address" limitation, and claim 23 teaches a programmable unique address.

On October 23, 1987-seventeen days after Schumann had argued to Examiner Trafton in the course of prosecuting the 278 application that "[n]one of the references either singularly or in combination teach or suggest ... the three node approach to communications as provided in the claimed inven-

--- F.3d ----

Page 10

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

tion"-Schumann had a telephonic interview with Examiner Lev to discuss his discovery of a previously-undisclosed prior art reference, U.S. Patent No. 4,456,793 ("the 793 patent") to Baker. J.A. at 653. Baker teaches a cordless telephone system in which a portable telephone handset (or station) communicates via optical transceivers with one of possibly several "subsystem controllers," which in turn communicate with a central controller. 793 patent col.2 ll.40-61. Baker also teaches the use of "unique codes for each subsystem and station within the subsystem." *Id.* col.3 ll.6-7. In light of these teachings, Examiner Lev suggested to Schumann that he cancel the newly added claims. J.A. at 653. Schumann neither agreed with Examiner Lev, nor disclosed the existence of Baker to Examiner Trafton.

\*6 In a December 1, 1987, office action, Examiner Lev again rejected all claims pending in the 149 application. Claim 19 was rejected as anticipated by U.S. Patent No. 4,569,421 ("the 421 patent") to Sunstedt, and claims 15, 16, and 21 through 23 were rejected as obvious in light of several new combinations of prior art references, including Blum and Sunstedt. J.A. at 656-58. Sunstedt teaches a vending system for use in restaurants in which a waiter wirelessly transmits a customer's order from a portable handheld terminal to an "input station" subject to intermittent polling by a polling station. 421 patent col.2 ll.64-67; *id.* col.3 ll.40-44. Once the information at the input station is detected by the polling station, the order is then transmitted to a local data processor which calculates the customer's bill. *Id.* col.3 ll.10-20. Thus, in Examiner Lev's opinion, Sunstedt's three-node communication system in combination with other prior art references, including Blum, rendered claims 15, 16, and 21 obvious. J.A. at 656-57. Examiner Lev was of the further opinion that the addition of Baker's unique address also rendered claims 22 and 23 obvious. J.A. at 657-58. Examiner Trafton had not considered these combinations of references during prosecution of the 278 application, and Schumann did not disclose any of these rejections to Examiner Trafton.

On June 17, 1988, Schumann responded to Examiner Lev's rejection by further narrowing application claim 15 to encompass only handheld terminals cap-

able of initiating communication themselves, as opposed to the system taught by Sunstedt requiring intermittent polling to initiate communication. J.A. at 669. In that same response, Schumann cancelled application claims 19-24. On December 19, 1988, Examiner Lev issued a notice of allowance for the eighteen remaining claims. The claims issued on July 18, 1989, as U.S. Patent No. 4,850,009 ("the 009 patent").

## C

On July 24, 1987, Schumann filed Application No. 07/078,195-a continuation in part of the 278 application. As with the 278, Examiner Trafton was the examiner assigned to the 195 application. Examiner Trafton allowed nine application claims on December 16, 1988, and the patent thereafter issued as U.S. Patent No. 4,835,372 ("the 372 patent"). The only independent claim of the 372 patent provides:

1. A patient identification and verification system for relating items to specific patients and for ensuring that an identified item corresponds to an identified patient, comprising:

- (a) programmed *system computer means* for processing and storing patient data;
- (b) input means operatively interconnected to the programmed system computer means for input of data to the programmed system computer means;
- (c) output means operatively interconnected to the programmed system computer means for output of data from the programmed system computer means;
- (d) first bar code identifier means adapted for attachment to a patient for identification of the patient, the bar code identifier means including a patient unique code;

\*7 (e) a plurality of second bar code identifier means for identifying items, the second bar code identifier means including a code different from that of the first bar code identifier means so as to differentiate between the first and second bar code identifier means;

(f) the input means and output means including:

- (i) microprocessor controlled *portable handheld patient terminal means* having bar code reader means for scanning the second bar code identifier means for relating various items to a specific patient, the portable handheld patient terminal means further includ-

--- F.3d ---

Page 11

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

ing keyboard and display means, the portable hand-held patient terminal means including electromagnetic wave transceiver means including means for transmission of data as an electromagnetic wave which is representative of the first and second bar code identifier means scanned by the bar code reader means and including means for receipt of data as an electromagnetic wave;

(ii) microprocessor controlled *base station means* including electromagnetic wave transceiver means for receipt of and transmission of data as an electromagnetic wave to the patient terminal means, the base station means being interconnected to the programmed system computer means at least in part by telephone lines for receipt and transmission of data on the telephone lines to the programmed system computer means; and

(iii) a plurality of stationary terminal means located at various stations remote from the programmed system computer means and interconnected to the programmed system computer means at least in part by telephone lines for transmitting data to the programmed system computer means and for receipt of data from the programmed system computer means; and

(g) terminal support means for interconnecting a bar code reading device, at least one printer device and a terminal having a display and keyboard to the system computer, the terminal support means including DOV modem means for transmission of data to the system computer at least in part by telephone wiring.

372 patent col.44 l.39-col.45 l.33 (emphasis added). As with the 716 patent, claim 1 of the 372 patent encompasses three-node communication. Prior to the issuance of the 716 patent, Schumann did not notify Examiner Trafton that the claims of the 372 patent had been allowed.

## II

McKesson initiated the present suit for infringement against Bridge on December 13, 2002, in the United States District Court for the Eastern District of California. Bridge answered McKesson's complaint by pleading the affirmative defenses of unenforceability due to inequitable conduct, equitable estoppel, and unclean hands. Bridge also brought counterclaims

against McKesson for declaratory judgment. The district court bifurcated the trial into two phases, with the first phase being a bench trial on the inequitable conduct affirmative defense and the second phase being a jury trial on the remainder of the claims, counterclaims, and affirmative defenses. A four-day bench trial of the first phase resulted in an unenforceability judgment in favor of Bridge, thereby rendering the second phase unnecessary.

\*8 The court issued its findings of fact and conclusions of law on June 13, 2006. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, No. 02-2669, 2006 WL 1652518 (E.D. Cal. June 13, 2006) ("*Findings and Conclusions*"). In particular, the court found by clear and convincing evidence that, in the course of prosecuting the 716 patent, Schumann's failures to disclose (1) the existence of the Baker patent, (2) Examiner Lev's rejections of the initially broad claims in the 149 application (which issued as the 009 patent), and (3) the allowance of claims in the 372 patent were material omissions done with an intent to deceive. *Findings and Conclusions*, slip op. at 16-48.

## A

With respect to Schumann's failure to disclose the Baker patent to Examiner Trafton, the court first noted that until Examiner Lev brought Baker to Schumann's attention, "the same 38 prior art references [had been cited] in the 716 and 009 prosecutions [*i.e.*, the 278 and 149 applications, respectively]." *Id.*, slip op. at 21. The court found this fact supportive of a finding of materiality because, as Schumann testified, "[i]f the same art had been before the examiners and the claims are substantially similar, [that is] probably a pretty good indication that the reference would be pretty material." *Id.* Another fact the court deemed significant was Examiner Lev's finding "that the Baker patent rendered the address code in the portable handheld [of the 149 application] obvious," *id.*, because, as Schumann admitted, the address code of the 149 application was the same as the "programmable unique identifier" limitation of the 278 application, *see id.*, slip op. at 21-22. Taken together, these two observations led the court to conclude that "the Baker patent meets the 'reasonable examiner' materiality standard and

--- F.3d ----

Page 12

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

should have been disclosed to Examiner Trafton.” *Id.*, slip op. at 22.

The court buttressed its materiality conclusion with the further observation that the Baker patent also includes three-node communication—the very type of communication Schumann used to differentiate the claims of the 716 patent from the prior art. *See id.*, slip op. at 23-24. The court explained, in accordance with expert testimony elicited at trial, that “Schumann could not have made this patentability argument if Examiner Trafton had the opportunity to consider the Baker patent.” *Id.*, slip op. at 24. Given this further observation, the court found the Baker patent to be not merely material, but “highly material.” *Id.*

McKesson offered several reasons why, in its view, Baker would not have been material to Examiner Trafton. First, McKesson contended to the district court that disclosure of the Baker patent would have been cumulative of other prior art because “other prior art references, the Blum and Hawkins patents.” *Id.* The Blum reference, U.S. Patent No. 4,628,193 (“the 193 patent”), describes a portable handheld device useful in a hospital setting. The user of Blum’s handheld device first plugs it into a central computer in order to download patient data. The user then unplugs the device and carries it from bed to bed, and uses the downloaded data to ensure that each patient receives the correct treatment and/or medication. 193 patent col.3 l.63–col.4 l.36. The Hawkins reference, U.S. Patent No. 4,593,155 (“the 155 patent”), describes a “portable ID code transfer system in which the portable unit learns its associated ID code from the base communication unit thereby eliminating any requirement for manually coding the portable unit with an ID code to match the base unit,” 155 patent col.1 l.66–col.2 l.4, useful for “portable telephone systems, garage door openers and remote computer terminals which communicate with a master computer,” *id.* col.1 ll.13–16. In the context of a portable telephone system, the Hawkins reference also describes communication between the base unit and an outside telephone network in the event that the portable unit and base unit have matching IDs. *Id.* at [57].

\*9 The district court found this argument unpersuas-

ive in part because “Lev, who already had both the Blum and Hawkins patents before him ..., added the Baker patent to the mix of prior art in the 009 prosecution, and then relied on it in rejecting claims to a portable handheld terminal.” *Findings and Conclusions*, slip op. at 25. “Clearly,” the court continued, “Examiner Lev did not view Baker as cumulative, but rather treated it as an important *addition* to the prior art previously cited by Mr. Schumann.” *Id.* (emphasis in original); cf. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed.Cir.1995) (holding that a district court did not clearly err in finding materiality where the prior art reference at issue had been considered material by examiners in related foreign patent applications). The court also viewed the Baker patent as “more explicitly and clearly disclos[ing] a three-node wireless communications system than either the Blum or Hawkins patents.” *Findings and Conclusions*, slip op. at 25. Reasoning that the Baker patent need not invalidate the claims of the 716 patent in order to be material, the district court thus found that a “reasonable examiner would have been substantially likely to consider the Baker patent important to the evaluation of the [’278] application” given “the similarity of the core features of the Baker patent to the subject matter of the 716 patent.” *Id.* Ultimately, then, the district court found Baker “highly material and not cumulative.” *Id.*, slip op. at 27.

The court next evaluated intent and found that Schumann did in fact intend to deceive Examiner Trafton by failing to disclose the Baker patent. The court first explained that intent was inferable because “Schumann was informed of the Baker patent’s materiality by the PTO itself when Examiner Lev brought the patent to [Schumann’s] attention, suggested cancellation of certain claims, and then rejected claims as obvious in light of Baker—including claim elements that were present in the [’278] application.” *Id.*, slip op. at 28. The court also reasoned that given the mere seventeen-day gap between Schumann’s “representation to Examiner Trafton that the prior art does not disclose the three-node approach to communications as provided in the claimed invention” and his telephonic discussion with Examiner Lev, “Schumann could not have (or certainly should not have) missed Baker’s significance [since] it rendered

# **Exhibit 45**

## **Part II**

--- F.3d ----

Page 13

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

his recent statement to Examiner Trafton untrue, further confirming that intent to deceive should be inferred.” *Id.*, slip op. at 28-29.

The court found additional evidence of deceptive intent in Schumann's admission at trial that he knew his duty to disclose material information continued for at least 22 months after he learned of the Baker patent, and yet Schumann did nothing to bring Baker to Examiner Trafton's attention. *Id.*, slip op. at 29. Moreover, the court explained, “Schumann himself evidenced his realization of the strength of the Baker patent when he chose not to even attempt to overcome Examiner Lev's rejection based on Baker and cancelled the claims in the [ 149] application that were rejected due to Baker.” *Id.* And because the cancelled claims “included, according to Mr. Schumann's own admission, aspects of the invention under review [by Examiner Trafton], Mr. Schumann either knew or should have known that the Baker patent was material in the 716 case.” *Id.*, slip op. at 30.

\*10 The court recognized Schumann's testimony that although “he has no recollection whatsoever of prosecuting the 716 patent,” he believes, “looking at the Baker reference now, [that] it is cumulative.” *Id.* However, the court found this explanation incredible both because it would have been unreasonable, in the court's opinion, to conclude that Baker is cumulative, and because no contemporaneous evidence (e.g., notes, records, files, etc.) was adduced at trial to show that Schumann actually analyzed Baker and arrived at such a conclusion. *Id.*, slip op at 31. The court further rejected Schumann's explanation as “strain[ing] credulity” in light of the sequence of events surrounding the Baker patent:

(1) Examiner Lev located the Baker patent on his own; (2) he brought it to Mr. Schumann's attention in a telephone interview; (3) he suggested the cancellation of certain 009 claims, and then issued a rejection of those claims based in part on Baker; (4) shortly thereafter, Mr. Schumann found that the rejection based on Baker could not be overcome, requiring him to cancel the claims (regarding a handheld patient terminal system communicating wirelessly with base stations and via wires with a remote central computer) in order to continue with the 009 prosecution; (5) finally, even though Mr. Schumann had disclosed

the same prior art in both the 009 and 716 prosecutions through that point in time, he concluded that the Baker patent had no bearing on the 716 prosecution (which involved the same three-node wireless system rejected in the 009 prosecution).

*Id.*, slip op. at 31-32. The court also discredited the testimony as inconsistent with Schumann's assertion on the witness stand that it was his practice to be “over inclusive” and to “bend[ ] over backwards to make sure [he] got everything into the case.” *Id.*, slip op. at 32. The totality of this evidence, according to the court, “overwhelmingly establishe[d]” that Schumann, by withholding the Baker patent from Examiner Trafton, acted with an intent to deceive. *Id.*, slip op at 33-34.

## B

As to Schumann's failure to disclose Examiner Lev's rejections of the claims in the 149 application, the court began its analysis by rejecting McKesson's argument that our decision in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed.Cir.2003), “created a *new* disclosure requirement that [did] not apply to Mr. Schumann's prosecution of the 716 patent in the 1980s.” *Findings and Conclusions*, slip op. at 34 (emphasis in original). Using *Dayco* as a guide, the court continued its analysis by explaining that Examiner Lev's “rejections are material if the rejected claims were ‘substantially similar’ to the claims pending before Examiner Trafton.” *Findings and Conclusions*, slip op. at 36 (quoting *Dayco*, 329 F.3d at 1368).

Based on this standard, the court found that Examiner Lev's February 26, 1987, rejection of claims 15 and 16 in the 149 application would have been important to Examiner Trafton's examination because those claims, which “disclosed all three nodes of the 716's patient identification system, with the identical means of communication among the core structures,” “substantially overlapped with the limitations of Claim 1 of the 716 patent.” *Findings and Conclusions*, slip op. at 37. Moreover, the court explained, this rejection would have been of additional importance to Examiner Trafton because it contradicts the argument for patentability Schumann made to Exam-

--- F.3d ----

Page 14

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

iner Trafton on October 6, 1987. *Id.*, slip op. at 38. The court further found materiality in Examiner Lev's December 1, 1987, rejection of claims 15, 16, 19, and 21 through 23 of the 149 application both because of the substantial similarity between those claims and claim 1 of the 716 patent, and because Examiner Lev "relied on the Baker patent, which had not been disclosed in the 716 prosecution, to reject the 'unique address' limitation of [claims 22 and 23], which was also a limitation of the 716 patent." *Id.*, slip op. at 37. This finding was buttressed by the court's observation that Schumann "acquiesced" to Examiner Lev's rejection by canceling claims 19 through 24. *Id.*, slip op. at 38. Here, too, the court reasoned that the rejection would have been of additional importance to Examiner Trafton because it contradicts Schumann's October 6 argument for patentability. *Id.*, slip op. at 38.

\*11 McKesson also argued, relying on our opinion in *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed.Cir.1998), that Schumann effectively disclosed Examiner Lev's rejections by disclosing the existence of the 149 application to Examiner Trafton. The district court rejected this argument by distinguishing *Akron Polymer* on its facts and by explaining that section 2001.06(b) of the Manual of Patent Examination and Procedure ("MPEP") as well as our decision in *Li Second Family LP v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed.Cir.2000), "plainly impose[ ] a duty of disclosure beyond citation of the co-pending application." *Findings and Conclusions*, slip op. at 39-40.

Regarding intent, Schumann's testimony at trial, according to the court, was that although he did not recall prosecuting the 278 application, he explained that "he probably did not believe activity in the [ 149] application was material to the 716 prosecution because the [ 149] case involved only a terminal, while the 716 involved an entire 'system.'" *Id.*, slip op. at 41. The court discounted this explanation as "contradicted by the actual wording of the claims rejected by Examiner Lev, which ... included all of the elements of a three-node wireless system." *Id.* Moreover, the court continued, "Schumann admitted on cross examination that his terminal/system argument was a distinction without a difference." *Id.* The court also discounted as not credible and the "product

of newly developed hindsight," Schumann's testimony that his firm at the time did not have procedures in place for citing office actions in co-pending applications. *Id.*, slip op. at 42. Schumann's trial testimony in this regard was further undermined, in the court's estimation, by his deposition testimony that a rejection in a co-pending application ought to be disclosed "if it was deemed to be relevant." *Id.* And even if Schumann's former firm did have such procedures in place (a matter not decided in fact), the court held that our decision in *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed.Cir.2001), prevents firms from "insulat[ing] [their attorneys] against charges of inequitable conduct by instituting policies that prevent [the attorneys] from complying with the law," *Findings and Conclusions*, slip op. at 43. Thus, the court concluded that "while Mr. Schumann's disclosure of the co-pendency of the [ 149 application] to Examiner Trafton is *some* evidence of a lack of intent to deceive under *Akron Polymer*, weighing all the evidence here, as the court must, said disclosure does not overcome the inference of an intent to deceive established [on these facts]." *Findings and Conclusions*, slip op. at 44 (emphasis in original) (footnote omitted).

### C

The district court next addressed Schumann's failure to disclose the allowance of the claims of the 372 patent. Again the court looked to *Dayco* and MPEP § 2001.06(b), and held that a notice of allowance in a co-pending application is material if the allowed claims could conceivably have given rise to a double patenting rejection. *Findings and Conclusions*, slip op. at 45-46. McKesson argued that, even so, the claims of the 716 patent are not sufficiently similar to the claims of the 372 patent to render the allowance of those claims material. The district court disagreed, finding that although the claims of the 372 patent do not have a comparable "programmable unique identifier" limitation, "Examiner Trafton should have been given the opportunity to consider whether the added limitations in the 716 were non-obvious." *Id.*, slip op. at 47. "Indeed," the court continued, "given that Examiner Lev had rejected the 'unique identifier' as obvious ..., it is certainly conceivable that the 716 could

--- F.3d ---

Page 15

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

have been rejected under the doctrine of obviousness-type double patenting.” *Id.* Thus, the court concluded that the allowance of the 372 claims was material and should have been disclosed.

\*12 As to intent, the court discounted Schumann’s explanation as “implausible” that “the two patents did not raise a double patenting issue because ‘the claims were different in those cases.’ ” *Id.*, slip op. at 48. Specifically, the court explained that because the structure of means-plus-function limitations are defined by the specification, and because “the entire 716 specification ... is included in the 372 specification,” “Schumann certainly should have known, if he did not know, that an allowance of identical claims might have been important to make of record.” *Id.* Even giving Schumann credit for disclosing the existence of the co-pending application that led to the 372 patent, the court nevertheless found that Schumann withheld the allowance of the 372 claims with deceptive intent.

### D

As a final step, the court engaged in equitable balancing and concluded that the “pattern of material nondisclosures, such as present here, weighs firmly in favor of unenforceability,” *id.*, because “the showings of materiality and intent are high” with respect to each identified nondisclosure, *id.*, slip op. at 50. The court thus entered judgment against McKesson on infringement and dismissed Bridge’s pending counterclaims as moot and without prejudice. McKesson subsequently appealed to this court. Because the district court disposed of all claims and counterclaims, its judgment is final and we have appellate jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). *See Int’l Elec. Tech. Corp. v. Hughes Aircraft Co.*, 476 F.3d 1329, 1330-31 (Fed.Cir.2007).

### III

[1] “A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313

(Fed.Cir.2006); *see also* 37 C.F.R. § 1.56(a) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”).

[2][3][4] The materiality of information withheld during prosecution may be judged by the “reasonable examiner” standard. *See id.* at 1316. That is, “[m]ateriality ... embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.” *Akron Polymer*, 148 F.3d at 1382 (citations omitted). Moreover, “[i]nformation concealed from the PTO may be material even though it would not invalidate the patent.” *Li Second Family*, 231 F.3d at 1380. “However, a withheld otherwise material [piece of information] is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner.” *Digital Control*, 437 F.3d at 1319. “As this court has previously noted, the scope and content of prior art and what the prior art teaches are questions of fact.” *Id.*

\*13 [5][6][7] “The intent element of the offense is ... in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.” *Akron Polymer*, 148 F.3d at 1385. “However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.” *Dayco*, 329 F.3d at 1367. In addition, “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed.Cir.1988) (en banc in relevant part).

[8][9] “The party asserting inequitable conduct must prove a threshold level of materiality and intent by

--- F.3d ---

Page 16

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

clear and convincing evidence.” *Digital Control*, 437 F.3d at 1313. “The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’ ” *Id.* (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed.Cir.2001)). “When, after a trial, the court has made factual findings as to materiality and deceptive intent, those factual findings are reviewed for clear error, and the decision of the ultimate issue of inequitable conduct is reviewed for abuse of discretion.” *Digital Control*, 437 F.3d at 1313.

## A

[10] We first discuss Schumann's failure to disclose the Baker patent to Examiner Trafton during prosecution of the applications leading to the 716 patent. McKesson first points out that Examiner Lev cited Baker “solely for its disclosure of a unique address code,” and that Hawkins, which was before Examiner Trafton, also discloses that same feature. Moreover, according to McKesson, “Hawkins is a *better and more relevant* reference with regard to the 716 prosecution because Hawkins further teaches a programmable unique identifier for wireless communications between a portable terminal and base station, as claimed in the 716,” unlike Baker, which allegedly “does not teach that critical feature of programming.” Appellant's Br. at 56 (emphasis in original). Therefore, McKesson contends, “Baker's disclosure of a unique address code was merely cumulative to Hawkins.” *Id.* at 57.

Even if McKesson is correct that Hawkins discloses a programmable unique identifier limitation more clearly than Baker, the importance of Baker to a reasonable examiner is not limited to the disclosure of that limitation. One of Schumann's primary arguments for the patentability of the claims of the 716 patent was the use of three-node communication. Accordingly, the three-node communication system disclosed in Baker—consisting of portable handsets, one or more subsystem controllers, and a central controller—could be material quite apart from the disclosure of anything analogous to a programmable unique identifier limitation.

\*14 Insofar as both patents disclose three-node communication, McKesson characterizes Hawkins as being on equal footing as Baker. We disagree. The Hawkins specification, which contemplates communication between a garage door opener and a remote control in one embodiment, leaves no doubt that the invention described therein is a two-node communication system consisting of a base station and a portable unit. Admittedly, in the wireless telephone embodiment, this system is capable of connecting to a third communication node, *i.e.*, a telephone system network. 155 patent col.21 ll.6-9 (claim 25). However, unlike the Baker patent, only two nodes are described in any significant detail in the Hawkins patent.

Moreover, the telephone system network node of the Hawkins patent is not the analogue to the central controller node in the Baker patent because the central controller node is an internal node entirely separate from any outside network node. In other words, the base station node in the wireless telephone embodiment of the Hawkins patent directly connects to the telephone system network node, but the analogous subsystem controller node in the Baker patent only indirectly connects with an outside network node via the central controller node. *See, e.g.*, 793 patent col.6 ll.28-38 (explaining that the “central controller 101 controls incoming and outgoing calls to a telephone central office”); *id.* fig. 3. Thus, we find no clear error in the district court's conclusion that Baker discloses three-node communication more clearly than Hawkins.

McKesson further argues that “the art of record showed at least twelve three-node systems” in order to demonstrate that Baker is cumulative. Appellant's Reply Br. at 10. However, aside from Hawkins (in combination with Blum), the only two such systems specifically pointed to by McKesson are U.S. Patent No. 4,588,881 (“the 881 patent”) to Pejas, and U.S. Patent No. 4,180,204 (“the 204 patent”) to Koenig. Appellant's Reply Br. at 10.

[11] Pejas relates to an inventory-monitoring system in which one or more bar code “reading pens” are each connected to their own portable terminal. 881 patent col.2 ll.20-24. The portable terminals commu-

--- F.3d ---

Page 17

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

nicate wirelessly with “converters” which, in turn, communicate with a “control centre.” *Id.* col.2 ll.24-37. The system facilitates communication between the control center and a particular terminal by associating an address with each terminal. *Id.* col.3 ll.15-27. Thus, Pejas appears to disclose both three-node communication (pen/terminal to converter to control center), as well as a unique addressing scheme analogous to the programmable unique identifier limitation of the 716 patent. Importantly, however, the description of the preferred embodiment in Baker spans over eleven columns and provides a highly technical discussion of the implementation of the three-node communication system with unique addressing, whereas the same description in Pejas is just under two columns and provides only cursory implementation details. Compare 793 patent col.4 l.33-col.15 l.46, with 881 patent col.2 l.15-col.4 l.12. Therefore, we find no clear error in the district court's failure to find that Pejas renders Baker cumulative.

\*15 [12] Koenig, the other reference identified by McKesson, discloses a similar pen-type reader, or “wand,” attached to a portable terminal for reading bar codes. 204 patent fig.1. When the wand successfully reads a bar code, the data is transmitted from the terminal to a remote computer via a modem. *Id.* col.3 ll.52-56. As a threshold matter, we question whether Koenig actually discloses a three-node communication system because it appears from the claims that the modem is not a distinct node. See *id.* col.6 ll.30-32 (stating that “said computer means comprises a minicomputer and a modem interface” (emphasis added)). In addition, Koenig does not disclose anything analogous to the programmable unique identifier limitation of the 716 patent. Accordingly, we hold that the district court did not clearly err by finding Baker noncumulative.

[13] McKesson advances another assignment of clear error by contending that the district court, in concluding that Baker undermines Schumann's argument to Examiner Trafton on October 6, 1987, that “none of the references [either singularly or in combination] teach the three node approach to communications as provided in the claimed invention,” J.A. at 366, misinterpreted Schumann's statement by focusing “solely on a comparison of the similarities of Baker and the

716 claims and not their differences,” Appellant's Br. at 60. According to McKesson, Schumann was not referring to three-node communication generally, but rather to three-node communication with all of the limitations present in the claims, i.e., “as provided in the claimed invention.” In particular, McKesson points out:

Bridge adduced no evidence that (a) the “central controller” of Baker “may have its own terminals for entry/display of information;” (b) the “subsystem controller” of Baker is “preferably located in the patient rooms and other suitable locations;” or (c) the cordless phone of Baker constitutes a “portable handheld patient terminal” including all the limitations thereof contained in the claims of the 716 patent.

Appellant's Reply Br. at 6.

We are not persuaded by this argument. Reading Schumann's statement to Examiner Trafton in context, Schumann was plainly referring to the differences between the three-node communication system of the 716 claims and non-three-node communication systems of the prior art, exclusive of any other differences between the claims and the prior art. See J.A. at 366 (“In addition to numerous other differences, none of the references teach the three node approach to communications as provided in the claimed invention.” (emphasis added)). Moreover, the existence of differences between Baker and the 716 claims does not, standing alone, render Baker immaterial. See *Li Second Family*, 231 F.3d at 1380 (“Information concealed from the PTO may be material even though it would not invalidate the patent.”). Thus, the district court did not clearly err in this regard.

\*16 McKesson contends that, irrespective of Baker's materiality, the district court clearly erred in finding that Schumann intended to deceive Examiner Trafton. In the proceedings below, the district court relied in part upon our decision in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348 (Fed.Cir.2005), to infer an intent to deceive. See *Findings and Conclusions*, slip op. at 27-28. In *Bruno*, we upheld a district court's finding of intent where prior art was withheld from the PTO but was nevertheless submitted to the FDA as part of that agency's product approval process. 394 F.3d at

--- F.3d ----

Page 18

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

1354. The high materiality of the withheld prior art coupled with the lack of “a credible explanation for the nondisclosure” led us to conclude that the district court had not committed clear error by inferring an intent to deceive. *Id.*, at 1354-55. In this case, the district court rejected as incredible Schumann's explanation for nondisclosure of the highly-material Baker reference.

McKesson believes *Bruno* is distinguishable from the present case for three reasons. First, McKesson argues, “the device disclosed to the FDA included a more relevant feature than any art of record in the patent-in-issue,” whereas in this case “the features disclosed in Baker were already present in the art of record.” Appellant's Br. at 61. We reject this argument because it is nothing more than an attempt to re-hash an argument rejected above, namely, that Baker is cumulative of the prior art that was already in front of Examiner Trafton.

The second distinction raised by McKesson is that “in *Bruno*, the patentee affirmatively disclosed the device to the FDA while simultaneously withholding it from the PTO,” but here, “Schumann made no comparable disclosure outside the PTO.” Appellant's Br. at 61. To begin with, we see no meaningful distinction between disclosure outside the PTO as opposed to disclosure within the PTO. With that in mind, we find *Bruno* to be on point because, as in that case, Schumann had closely related co-pending applications (the 278 application and the 149 application) in which a noncumulative, material prior art reference (Baker) was withheld from one examiner (Trafton) but was simultaneously in front of the other examiner (Lev).

Finally, McKesson points out that “the device disclosed to the FDA in *Bruno* was a ‘substantial equivalent’ of the product containing the patented technology,” but in this case, there is no such substantial equivalence because the Baker patent relates to a cordless telephone system and the 716 patent relates to a patient identification and verification system. Appellant's Br. at 61. McKesson reads too much into *Bruno*. We did not hold in that case that substantial equivalence is necessary to support a finding of inequitable conduct; we merely found that substantial

equivalence is sufficient. In other words, we did not hold that a prior art reference must be substantially equivalent to the claimed invention in order to be material.

\*17 McKesson also attempts to seek refuge from *Bruno* by looking to our holding in *Akron Polymer*. In *Akron Polymer*, co-pending applications were being prosecuted by the same attorney to different examiners. The prosecuting attorney disclosed the first-filed application to the examiner of the second-filed application, but did not disclose the filing of the second application to the examiner of the first-filed application. In the first trial of the case, the district court held that the second application was not material to the prosecution of the first-filed application. The district court also found no culpable intent on behalf of the common applicant and thus no inequitable conduct. On appeal, we disagreed, holding that the second-filed application was highly material to the prosecution of the first-filed application, because “it could have conceivably served as the basis of a double patenting rejection.” *Akron Polymer*, 148 F.3d at 1382. We thus remanded for further adjudication of the inequitable conduct issue. *Id.*

On remand, the district court found deceptive intent with regard to nondisclosure of the second application to the examiner of the first-filed application. The patentee appealed the judgment of inequitable conduct, arguing error in the finding of deceptive intent. We noted that “[w]hen examining intent to deceive, a court must weigh all the evidence, including evidence of good faith.” *Id.* at 1384. Because the district court had given no weight at all to the inference of good faith that had to be drawn from disclosure of the second application, we found clear error in the district court's assessment of culpable intent. Consequently, we reversed the judgment of unenforceability.

*Akron Polymer* stands for no more than the unsurprising proposition that all evidence of intent, including all inferences, favorable and unfavorable, must be weighed when assessing culpable intent. In that case, the district court overlooked a favorable inference that should have been drawn in favor of the patentee. That error undermined the judgment of unenforceability.

--- F.3d ----

Page 19

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

ility.

We agree with McKesson's assertion that *Akron Polymer* earns it some credit for the fact that Schumann did disclose the co-pendency of the 149 application to Examiner Trafton in the assessment of the overall inferences to be drawn from all the facts in the case. The district court did in fact credit McKesson with "some evidence of a lack of intent to deceive under *Akron Polymer*." *Findings and Conclusions*, slip op. at 44; see also *id.*, slip op. at 48 (giving Schumann credit for disclosing the co-pendency of the application that issued as the 372 patent). But the district court weighed all the evidence, as discussed above in this opinion, and held that the favorable inference drawn from disclosure of the second application "does not overcome the inference of an intent to deceive established by the [other] facts." *Id.*, slip op. at 44.

\*18 McKesson continues by contending that Schumann did not know and should not have known of Baker's materiality because Examiner Lev cited it during prosecution of the 009 patent "only ... for its unique addressing feature that was already before Examiner Trafton in the better disclosure of Hawkins." Appellant's Br. at 62. Moreover, McKesson states, the seventeen-day gap between Schumann's October 6 assertion to Examiner Trafton that none of the prior art teaches three-node communication and Schumann's October 23 interview with Examiner Lev regarding Baker "cannot be evidence of intent," given that the assertion to Examiner Trafton was before the interview with Baker. *Id.*

[14][15] These two arguments are unconvincing. As to the former, simply because Examiner Lev cited Baker for its unique addressing feature did not release Schumann from the relevance of Baker's other teachings. Although McKesson's argument might have some merit if Examiner Lev had cited one small section of a much larger work, citation to the eighteen-column Baker patent put Schumann on notice of the content of the whole document. And as to the second argument, Schumann's duty to disclose material information to the PTO extended well beyond October 23, 1997. See, e.g., *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803

(Fed.Cir.1991) ("The duty of candor extends throughout the patent's entire prosecution history."); MPEP § 2001.06 (5th ed. rev.3, 1986) ("The duty to disclose material information extends to information [individuals covered by 37 C.F.R. § 1.56] are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof."). Therefore, the fact that Schumann learned of Baker after his October 6 assertion to Examiner Trafton is of no consequence. The mere seventeen-day gap is important, however, because it bolsters the district court's inferences that Schumann knew or should have known of Baker's materiality to the 278 application, and that he intentionally withheld Baker from Examiner Trafton with deceptive intent.

[16] We also reject McKesson's attempt to downplay the significance of Schumann's cancellation of claim 22 of the 149 application subsequent to Examiner Lev's citation to Baker. Irrespective of Schumann's disagreement with Examiner Lev's conclusion that claim 22—which incorporated both three-node communication and a unique address limitation—was obvious in light of a combination involving Baker, Schumann's cancellation of that claim fairly gives rise to an inference that he recognized Baker would also present a significant obstacle to the patentability of dependent claim 6 of the 278 application. Yet, in spite of the advice provided to prosecuting attorneys in the 1986 version of the MPEP that "information ... specifically considered and discarded as not material" ought to be "recorded in [the] attorney's file or applicant's file, including the reason for discarding it," MPEP § 2004(18) (5th ed. rev.3, 1986),<sup>FN1</sup> Schumann offered no such recorded reason; he was only able to give speculative testimony about the conclusions he must have drawn at the time with respect to Baker's materiality. The district court, as it was free to do, found this testimony incredible. *Findings and Conclusions*, slip op. at 31-32. Accordingly, we see no clear error in the district court's inference of intent from Schumann's cancellation of claim 22.

\*19 [17] Finally, McKesson asserts that *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed.Cir.1997), is distinguishable. In that case, we found an intent to deceive where an applicant knowingly failed to disclose a prior art patent during

--- F.3d ---

Page 20

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

prosecution that recited a limitation corresponding to “a point of novelty the examiner relied upon during the course of prosecution.” *Id.*, 120 F.3d at 1256. McKesson primarily distinguishes the case at hand by stating that Baker does not disclose a “point of novelty” of the 716 claims, and that the evidence does not show that Schumann understood Baker to disclose any such point of novelty. Both of these points of distinction are incorrect. As we explained above, Baker discloses two of the 716 patent's points of novelty: three-node communication and unique addressing. In addition, the evidence unquestionably shows that Schumann understood Baker to disclose at least unique addressing, and that Schumann should have understood Baker to disclose three-node communication. Therefore, the district court did not clearly err by further inferring deceptive intent from Schumann's subsequent failure to disclose Baker to Examiner Trafton. As the district court held, the overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure of Baker, supports the finding of deceptive intent. *Findings and Conclusions*, slip op. at 27.

## B

We now turn to Schumann's failure to disclose Examiner Lev's rejections in the 149 application ('009 patent). This court addressed the failure to disclose rejections in co-pending applications for the first time in *Dayco*. We held that:

[A] contrary decision of another examiner reviewing a *substantially similar* claim meets the *Akron Polymer* “reasonable examiner” threshold materiality test of “any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.” 148 F.3d at 1382, 47 U.S.P.Q.2d at 1534 (emphasis in original). Patent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ when interpreting such documents. Although examiners are not bound to follow other examiners' interpretations, knowledge of a potentially different interpretation is clearly information that an examiner could consider important when examining an application.

*Dayco*, 329 F.3d at 1368 (first emphasis added).

In the proceedings below, McKesson urged the district court to hold that a “substantially similar” claim is a claim having substantial similarity “in content and scope” to the claim at issue. The court declined, explaining first that the phrase “in content and scope” was not used by this court in *Dayco*, and second that “McKesson has not provided any persuasive explanation for how this language substantively alters the result here.” *Findings and Conclusions*, slip op. at 36 n. 7. Instead, the court announced that it would apply a “substantially similar” test in determining whether “there is a substantial likelihood that a reasonable examiner would have considered the [rejections] important in deciding whether to issue the application as a patent.” *Id.* at 17, 36 n. 7. The court further noted that we found substantial similarity in *Dayco* among claims that “were in some respects substantially identical.” See *Dayco*, 329 F.3d at 1361 (emphasis added). McKesson argues on appeal that the district court misapplied *Dayco* because it used a lesser “in some respects identical” test which failed to account for differences between the compared sets of claims.

\*20 [18][19][20] As we explained in *Digital Control*, materiality may be proven in numerous ways, including via the so-called “reasonable examiner” standard. 437 F.3d at 1316. Under *Dayco*, that standard is satisfied in the rejected-claims setting if the rejected claims are substantially similar to the claims at issue. 329 F.3d at 1368. In other words, a showing of substantial similarity is *sufficient* to prove materiality. It does not necessarily follow, however, that a showing of substantial similarity is *necessary* to prove materiality. Indeed, in the same way that prior art need not be substantially similar in order to be material (e.g., the telephone system of Baker, though not substantially similar to the 716 claims, is nevertheless material), rejected claims in a co-pending application also need not be substantially similar in order to be material. Therefore, to the extent there is a difference among “in some respects identical,” “substantially similar,” and substantial similarity “in content and scope,” that difference is inconsequential so long as the evidence clearly and convincingly proves materiality in one of the accepted ways. See *Digital Control*, 437 F.3d at 1316. Here, the district court found

--- F.3d ----

Page 21

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

under the accepted “reasonable examiner” standard that Examiner Lev’s rejection of certain 149 claims was in fact material to the prosecution of the 278 application before Examiner Trafton. Our role on appeal is to determine whether that finding is clearly erroneous.

[21] As to the district court’s finding of materiality with respect to Examiner Lev’s rejection of claims 15 and 16 in the 149 application on February 26, 1987, McKesson points to four differences between those claims and the claims of the 716 patent which McKesson argues were ignored by the district court:

[T]he portable handheld terminal system of claims 15-16[1] lacks a first and second bar code identifier means, [2] lacks the base station limitations of a programmable unique identifier, a means for allowing communication with a portable terminal having a corresponding unique identifier and a means for programming the portable terminal with the unique identifier, [3] lacks any patient identification or verification limitations, and [4] lacks any means for an alarm signal if the patient-item verification does not correspond.

Appellant’s Br. at 26-27. According to McKesson, these differences, combined with the fact (alleged by McKesson) that the three-node communication system disclosed in claims 15 and 16 is cumulative of prior art already before Examiner Trafton, demonstrates that Examiner Lev’s rejection of those claims would not have been of “any particular relevance to Examiner Trafton in the 716 prosecution.” *Id.* at 27.

We find this argument unpersuasive. We note as an initial matter that the district court did not ignore the differences cited above; rather, the court explicitly mentioned McKesson’s “redline” comparisons of the various claims to demonstrate that there are wording differences, and even some differences in claim limitations,” and then explained the rationale for rejecting those differences as insufficient to undermine a finding of materiality. *Findings and Conclusions*, slip op. at 36. Moreover, even if the district court’s opinion had not adequately addressed the differences pointed to by McKesson, we would not be inclined to find clear error as a result. Both the version of claims 15 and 16 rejected by Examiner Lev on February 26,

1987, as well as the version of the 278 application claims rejected by Examiner Trafton on April 6, 1987, unquestionably disclose three-node communication, the existence of which, as Schumann’s subsequent statements to Examiner Trafton reveal, was crucial to Schumann’s patentability argument. It is therefore evident that prior to Examiner Trafton’s April 6 rejection, Examiner Lev’s rejection of three-node communication would have been considered important by any reasonable examiner in Examiner Trafton’s position. And after April 6, when Examiner Trafton did not cite any combination of Blum and Pejas-as he would in the subsequent December 8 office action-the materiality of Examiner Lev’s rejection was arguably magnified. Lest there be any doubt as to the materiality of Examiner Lev’s rejection, we note that on August 26, 1987, Schumann responded to Examiner Lev by limiting the three-node system of the 149 application to “real time” communication, *see* J.A. at 649, and on October 6, 1987-just over one month later-he sought to overcome Examiner Trafton’s rejection with a nearly identical argument limiting the three-node system of the 278 application to “*real time*, interactive three node communication,” *id.* at 367 (emphasis added). Moreover, any differences between the three-node, bar code reading systems of the 278 application and the related 149 application are plainly less significant than the obvious differences between the three-node bar code reading systems of either application and the three-node telephone system of Baker. Yet, in spite of the obvious differences presented by the latter system, we held above that Baker is material. It must be the case, then, that the four differences pointed to by McKesson are insufficient to deprive Examiner Lev’s February 26 rejection of materiality. Along those same lines, and in light of our holding above that Baker is not cumulative, we must likewise hold here that any citation to Examiner Trafton regarding Examiner Lev’s February 26 rejection would not have been cumulative.

\*21 We arrive at the same conclusion with respect to Examiner Lev’s rejection of claims 15 and 16 on December 1, 1987, in view of a combination of Blum and Sunstedt. As we stated above, Schumann sought to overcome this rejection by further limiting the

--- F.3d ---

Page 22

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

three-node system of the 149 application to handheld terminals that do not require the polling taught by Sunstedt, but rather are capable of initiating communication themselves. It is at best unclear whether the claims of the 716 patent are similarly limited, or whether the initiation of communication by the handheld terminal which seems to be described in the specification is merely part of a preferred embodiment. *See, e.g.*, 716 patent col. 15 ll.12-18 ("Next, the nurse will read the patient identifier bar code on the patient's identification bracelet and the item identifier bar code on the items to be administered and press a 'SEND' key on the bar code reading device 48 while in the patient's room. This activates the transmission of data via the telephone wiring to the computer system 42."). Suffice it to say, it is substantially likely that Examiner Lev's rejection of the closely-related three-node system in the 149 application in view of Blum and Sunstedt would have been considered important to a reasonable examiner confronting the claims of the 278 application. And as before, the materiality of this rejection was arguably magnified by the fact that Examiner Traflet never cited any combination of Blum and Sunstedt before deciding to issue a notice of allowance.

[22][23] With respect to Examiner Lev's rejection of claims 19 and 21 through 23 in the same December 1 office action, McKesson raises a few additional materiality arguments we have not yet addressed. The first of those is McKesson's argument that Examiner Lev's rejection of claims 21 through 23 is immaterial because those claims recite a *method* of three-node communication, whereas claim 1 of the 716 patent recites a *system* for three-node communication. However, McKesson merely asserts in conclusory fashion that the method of claims 21 through 23 in the 149 application is "very different" from the system of claim 1 in the 716 patent. Appellant's Br. at 29. Because we disagree with this characterization, we conclude that this argument is simply a distinction without a difference. *See Li Second Family*, 231 F.3d at 1376 (affirming a finding of inequitable conduct where an applicant for semiconductor structure claims misrepresented the PTO's previous disposition with respect to related method of manufacture claims in another application pending before a different ex-

aminer). McKesson also argues that Schumann's cancellation of these claims in the face of Examiner Lev's rejection is not evidence of materiality because such cancellation is "a legitimate and acceptable practice to obtain an early issuance of a patent," and because Schumann "explicitly stated that he was *not* acquiescing in the rejection but reserving the right to bring the claims in a further application." Appellant's Br. at 30 (emphasis in original). While these facts may be evidence that Schumann disagreed with Examiner Lev, Schumann's cancellation of the claims remains evidence that Examiner Lev's rejections could not be easily overcome. As such, we see no error with the district court's conclusion that Schumann's cancellation-whether it is characterized as "acquiescence" or "legitimate and acceptable practice"-is evidence of materiality. Finally, McKesson points out that because rejected claim 19 discloses two-node communication, instead of three-node communication, Examiner Lev's rejection of that claim is not material. At most, this distinction demonstrates that Examiner Lev's rejection of claim 19 is cumulative because two-node communication was well known in the prior art, *e.g.*, the Hawkins patent. Nevertheless, we do not believe that the possibility of one small piece of evidence being cumulative is sufficient to undermine the legitimacy of the district court's otherwise error-free finding of materiality.

\*22 [24] As to intent, McKesson first argues that the district court mischaracterized the "terminal/system" distinction to which Schumann testified at trial. In fleshing this argument out, McKesson states that "[e]vidence that [Schumann] acted in concert with a belief that the 149 claims pertained to a *portable terminal*, or even a *portable terminal system*, and not the patient identification and verification system of the 716, shows a lack of deceptive intent that the court should not have ignored." Appellant's Br. at 35-36 (emphasis in original). Based on this explanation, we are unable to comprehend exactly how the district court mischaracterized Schumann's testimony. As best we are able to discern, McKesson's explanation makes exactly the same distinction between terminal claims and system claims. In any event, a comparison of the rejected claims to the 716 claims reveals that both sets of claims relate to the use of three-node

--- F.3d ----

Page 23

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

communication and a unique address in the context of bar code reading. Therefore, we conclude that the district court did not err in rejecting this distinction. *Cf. Li Second Family*, 231 F.3d at 1376.

[25] McKesson contends that the district court erred by failing to account for evidence of Schumann's good faith, namely, his two separate disclosures of the existence of the 149 application to Examiner Trafton in the course of prosecuting the 716 patent. According to McKesson, given the state of the law in the mid-1980s, "there was no awareness" that the further disclosure of rejections in co-pending applications was necessary. Appellant's Br. at 39. It was not until this court's 2003 decision in *Dayco*, McKesson argues, that the patent bar was put on notice that rejection disclosures are in fact necessary.

This argument is untenable in light of not only the facts of *Dayco* itself-where we applied this "new" law to patents claiming a priority date of 1989, *see* 329 F.3d at 1360-but also the then-current Fifth Edition of the MPEP, which explains the breadth of "information" as used in 37 C.F.R. § 1.56(a):

The term "information" as used in § 1.56 means all of the kinds of information required to be disclosed and includes *any* information which is "material to the examination of the application."

...

The term "information" is intended to be *all encompassing* .... [Section 1.56(a) ] is *not limited to information which would render the claims unpatentable*, but extends to any information "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

MPEP § 2001.04 (5th ed. rev.3, 1986) (emphasis altered). And in explaining the various sources of information subject to the duty to disclose, the MPEP further provides: All individuals covered by § 1.56 ... have a duty to disclose to the Patent and Trademark Office *all* material information they are aware of, or reasonably should have been aware of ..., *regardless of the source* of or how they became aware of the information. *Materiality controls* whether information must be disclosed to the Office, not the circumstances under which or the source from which the informa-

tion is obtained. If material, the information must be disclosed to the Office. The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application *or become aware of during the prosecution thereof*.

\*23 Such individuals may be or become aware of material information from various sources such as, for example, co-workers, tradeshow, communications from or with competitors, potential infringers or other third parties, related foreign applications ..., prior or *copending United States patent applications* ..., related litigation ... and preliminary examination searches.

MPEP § 2001.06 (5th ed. rev.3, 1986) (emphasis altered). The MPEP also makes clear that the above explanations apply with full force to information obtained with respect to co-pending applications: The individuals covered by 37 C.F.R. 1.56(a) have a duty to bring to the attention of the examiner ... *information* within their knowledge as to other copending United States applications which are "material to the examination" of the application in question.

MPEP § 2001.06(b) (5th ed. rev.3, 1986) (emphasis added). Thus, the MPEP to which Schumann would have referred <sup>FN2</sup> while the 278 application was pending leaves no doubt that material rejections in co-pending applications fall squarely within the duty of candor.

McKesson also attempts to distinguish the present facts from those found in *Li Second Family*. That case involved a complicated family of applications, all relating to semiconductors, dating as far back as 1965. *Li Second Family*, 231 F.3d at 1375-76. During prosecution of one application in the family, the examiner rejected the claims in light of three prior art references. *Id.* at 1376. The applicant responded by claiming that he was entitled to a priority date predating that of any of the references. *Id.* In September 1979, the examiner determined that the applicant was not entitled to the earlier priority date, and again rejected the claims. *Id.* The then-existing PTO Board of Appeals affirmed in 1981. *Id.* However, in 1984 during prosecution of another application in the family, the applicant presented the same priority date argu-

--- F.3d ---

Page 24

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

ment to a different examiner in order to overcome a rejection based on a set of prior art references that overlapped with the set of references that served as the basis for the rejection in the prior application. *Id.* at 1377. In so arguing, the applicant “made reference to the [prior] application only in a genealogy chart of the related applications that he attached to the last supplemental amendment he filed,” but made “no written record of a disclosure to the PTO ... of the Board's 1981 decision regarding priority dates in the [prior] application.” *Id.* Unlike the examiner in 1979, the examiner in this later application accepted the applicant's argument and allowed the claims with the earlier priority date. *Id.* After the patent issued, the applicant-turned-patentee filed an infringement suit against a competitor. *Id.* The competitor-defendant pled unenforceability due to inequitable conduct. *Id.* The district court agreed, finding that the patentee had “not adequately disclose[d] the [1981] decision to the [later] examiner and that [the patentee] further committed inequitable conduct by affirmatively and repeatedly arguing to the examiner that his claims were entitled to the benefit of the earlier filing date[ ].” *Id.*

\*24 On appeal, we stated that “[a]lthough the genealogy chart filed [with the last supplemental amendment] shows the chain of parent applications and related applications, including the [prior application subject to rejected priority dates], we agree with [the defendant] and the district court that the chart does not adequately disclose the relevant information—the Board's decision regarding the priority dates.” *Id.* at 1378. We explained that “[u]nlike an applicant's disclosure of a prior art reference, the content of which is presumed to be before the examiner, ... submission of the genealogy chart, with reference to the [prior] application only in the context of prior art cited in that application and with no mention of the Board's decision, was not sufficient to disclose the Board's decision to [the examiner].” *Id.* at 1379. “Moreover,” we continued, “in the same supplemental amendment to which [the then-applicant] attached the genealogy chart, [he] reiterated his assertions that the claims were entitled to filing dates of parent applications, a statement inconsistent with the Board's decision that [he] purportedly disclosed.” *Id.* After we then held

that the district court had not clearly erred in finding that the Board's decision in the prior application was material, *id.* at 1379-81, we proceeded to analyze the district court's finding of intent. We first explained that the numerous statements during prosecution contrary to the Board's decision supported a finding of intent to deceive. *Id.* at 1381. We next explained that the submission of the genealogy chart without disclosing the Board's decision was not evidence of good faith. *Id.* Consequently, we affirmed the district court's finding of intent. *Id.*

[26] McKesson believes the present case is significantly different from *Li Second Family* because that case involved affirmative misrepresentation of the Board decision, “which is far different than Schumann's facts.” Appellant's Br. at 40. We disagree. Here, as in *Li Second Family*, we are presented with a situation in which (1) the examiner of one application (Trafton) was not apprised of the adverse decisions by another examiner (Lev) in a closely-related application; (2) the applicant disclosed the closely-related application only in the context of prior art cited in that application, but failed to mention the adverse decisions; and (3) the applicant made statements to the examiner inconsistent with the other examiner's decisions, *i.e.*, that nothing in the prior art disclosed three-node communication. Given such a tight correlation between the facts at hand and those in *Li Second Family*, we must reject McKesson's attempt to distinguish that case. Accordingly, we hold that the district court did not clearly err in finding that Schumann intended to deceive the PTO by not disclosing the two rejections in the 149 application to Examiner Trafton.

### C

[27] With respect to Schumann's failure to notify Examiner Trafton of the allowance of the 372 patent claims, McKesson contends that the district court erred in its materiality analysis by failing to determine whether the differences between the allowed claims of the 372 patent and the claims of the 716 patent are “so inconsequential [that] there was a substantial likelihood a reasonable examiner would have issued a double patenting rejection.” Appellant's Br. at 45. McKesson thus proposes that the allowance of

--- F.3d ---

Page 25

--- F.3d ---, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ---)

the 372 patent could only be material to Examiner Trafton if he would have been likely to reject the 716 patent for double patenting. We disagree. Material information is not limited to information that would invalidate the claims under examination. *Li Second Family*, 231 F.3d at 1380. "As stated, the test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability." *Id.* With that test for materiality in mind, the district court's stated basis for finding materiality-the conceivability of a double patenting rejection-is not incorrect because allowance of the three-node system of the 372 patent claims plainly gives rise to a *conceivable* double patenting rejection, particularly in light of Examiner Lev's conclusion during examination of the 149 application that the addition of Baker's unique address limitation to the three-node system of Sunstedt was obvious. J.A. at 657-58. Under the correct test for materiality, the allowance of claims to a three-node communication system is material.

\*25 [28] Another perceived error pointed to by McKesson is the district court's alleged failure to consider the fact that Examiner Trafton was the examiner who allowed the 372 claims, and that he did so within a few months of allowing the 716 claims. It is unclear whether McKesson is arguing that this alleged failure undermines the district court's finding of materiality or its finding of intent. *Compare* Appellant's Br. at 48 (materiality), *with* Appellant's Reply Br. at 30-31 (intent). If this argument goes to materiality, it must fail because, as stated above, the allowance of the 372 claims is material. The most McKesson can argue is that the allowance is cumulative by virtue of the fact that Examiner Trafton, as the 278 examiner, probably remembered allowing the 372 claims and then realized the materiality of such allowance to the 278 application claims. However, because the record is devoid of any evidence in this regard, we cannot conclude that the allowance is cumulative. *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1564 (Fed.Cir.1984) ("[T]he district court did not *find* actual knowledge by the primary examiner-it merely noted possibilities and, where inequitable conduct is at issue, mere *possibilities* are insufficient.")

(emphasis in original). Moreover, the MPEP at the time explained that a prosecuting attorney should not "assume that [a PTO examiner] retains details of every pending file in his mind when he is reviewing a particular application," MPEP § 2001.06(b) (5th ed. rev.3, 1986) (quoting *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779 (7th Cir.1972)), and PTO regulations required all disclosures to be in writing, 37 C.F.R. § 1.2; *see also* MPEP § 2002.02 (5th ed. rev.3, 1986). Schumann thus was not entitled to assume that Examiner Trafton would recall his decision to grant the claims of the 372 patent when he was examining the 278 application in the absence of a written disclosure to that effect. If, on the other hand, McKesson makes this argument to undermine intent, the argument fails as a factual matter because Schumann specifically testified that he did not consider the identity of the examiner in deciding whether to disclose information about co-pending applications. J.A. at 2329-30.

As to the remainder of McKesson's arguments respecting the 347 patent, we find them duplicative of arguments we have already rejected in the context of the Baker patent and Examiner Lev's rejections in the course of examining the 149 application. Accordingly, we find no clear error in the district court's finding of materiality and intent.

#### D

As to the final step of balancing of materiality and intent undertaken by the district court, it appears that McKesson does not charge the court with abusing its discretion, and in any case, we find no such abuse.

[29] It is not necessary to decide whether any one of the three nondisclosures, standing alone, would have been sufficient to justify a judgment of unenforceability; in light of the district court's finding that there was inequitable conduct in all three instances, we hold that the court did not abuse its discretion in holding the patent unenforceable.

#### IV

\*26 Having found no clear error in any of the district court's findings with respect to materiality or intent, or in its balancing thereof, we must therefore affirm

--- F.3d ----

Page 26

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

(Cite as: --- F.3d ----)

the court's ultimate finding that the 716 patent is unenforceable due to inequitable conduct before the PTO.

#### AFFIRMED

NEWMAN, Circuit Judge, dissenting.

I respectfully dissent. It is not clear and convincing evidence of deceptive intent that the applicant did not inform the examiner of the examiner's grant of a related case of common parentage a few months earlier, a case that was examined by the same examiner and whose existence has previously been explicitly pointed out by the same applicant. Nor is it clear and convincing evidence of deceptive intent that the applicant did not cite a reference that the applicant had cited in the same related case, and that had been explicitly discussed with the same examiner in the related case.

Whether or not the examination was perfect, invalidation based on the charge of withholding material information for purposes of deception requires more than was here shown. To avoid the inequity resulting from litigation-driven distortion of the complex procedures of patent prosecution, precedent firmly requires that the intent element of inequitable conduct must be established by clear and convincing evidence of deceptive intent-not of mistake, if there were such, but of culpable intent. See *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed.Cir.1988) (*en banc*) (both materiality and intent to deceive must be proven); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed.Cir.1995) (proof of "clear and convincing" is necessary to establish intent to mislead or deceive the PTO). In *Kingsdown*, we observed that, "To be guilty of inequitable conduct, one must have intended to act inequitably." 863 F.2d at 872 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed.Cir.1987)). That standard was not met here. This court returns to the "plague" of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.

FN1. The full text reads:

18. Finally, if information was specifically

considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

MPEP § 2004(18) (5th ed. rev.3, 1986).

FN2. "[A]lthough [the MPEP] does not have the force of law, [it] is well known to those registered to practice in the PTO and reflects the presumptions under which the PTO operates." *Critikon*, 120 F.3d at 1257.

C.A.Fed. (Cal.),2007.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc.

--- F.3d ----, 2007 WL 1452731 (C.A.Fed. (Cal.)), 82 U.S.P.Q.2d 1865

END OF DOCUMENT

# Exhibit 46

Westlaw.

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

In re Metoprolol Succinate Patent Litigation  
 E.D.Mo.,2006.

Only the Westlaw citation is currently available.

United States District Court,E.D. Missouri, Eastern  
 Division.

In re METOPROLOL SUCCINATE PATENT LITIGATION  
 No. MDL NO. 1620.

Jan. 17, 2006.

Henry J. Renk, Jacob K. Baron, Lisa B. Pensabene, Robert L. Baechtold, Scott K. Reed, Tara A. Byrne, Fitzpatrick and Cella, New York, NY, Monica J. Allen, Robert T. Haar, Maggie B. Peters, Haar and Woods, LLP, St. Louis, MO, Jack B. Blumenfeld, Maryellen Noreika, Morris and Nichols, Wilmington, DE, for Plaintiffs.

Anita Pamintuan Fusco, Charles A. Weiss, Michael J. Freno, Richard L. Delucia, Kenyon and Kenyon, Alan B. Clement, Martin P. Endres, Nicholas P. Chiara, Hedman and Costigan, P.C., Richard D. Margiano, Martin B. Pavane, William A. Alper, Cohen and Pontani, New York, NY, Charles A. Weiss, Daniel A. Crowe, Bryan Cave LLP, John H. Quinn, III, Jeffrey H. Kass, Armstrong Teasdale, LLP, St. Louis, MO, Madeline S. Baio, Marshall and Dennehey, Philadelphia, PA, Steven A. Maddox, Foley & Lardner, Washington, DC, Paul J. Puricelli, Stone and Leyton, Clayton, MO, Kevin J. Connors, Marshall and Dennehey, George H. Seitz, III, Patricia P. McGonigle, Seitz and Van Ogtrop, P.A., Wilmington, DE, for Defendants.

#### MEMORANDUM AND ORDER

SIPPEL, J.

\*1 Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (collectively Astra) own patents claiming the pharmaceutically active compound metoprolol succinate and "sustained release" forms of that drug.<sup>FN1</sup> Defendants are drug makers seeking approval from the Federal Drug Administration to market extended release dosages of metoprolol succinate. Astra filed multiple lawsuits seeking declaratory judgments that Defendants' products infringe

upon Astra's patents. Defendants have moved for summary judgment contending Astra's patents are invalid and/or are unenforceable. Because I find that the patents are invalid based on double patenting and anticipation I will grant Defendants' motion for summary judgment on those grounds. Because I find that Astra engaged in inequitable conduct during the prosecution of the patents I will also grant Defendants' motion for summary judgment on that ground.

FN1. The record before me established that AstraZeneca LP is the owner of the patents in suit. The legal standing of the other two Plaintiffs has never been formally explained by the parties.

#### Legal standard

Defendants have moved for summary judgment on Astra's claims. In considering whether to grant summary judgment, a district court examines the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any...." Fed.R.Civ.P. 56(c). Summary judgment is appropriate if the evidence, viewed in the light most favorable to the nonmoving party, demonstrates that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Lynn v. Deaconess Medical Center*, 160 F.3d 484, 486 (8th Cir.1998)(citing Fed.R.Civ.P. 56(c)). The party seeking summary judgment bears the initial responsibility of informing the court of the basis of its motion and identifying those portions of the affidavits, pleadings, depositions, answers to interrogatories, and admissions on file which it believes demonstrates the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

When such a motion is made and supported by the movant, the nonmoving party may not rest on his pleadings but must produce sufficient evidence to support the existence of the essential elements of his case on which he bears the burden of proof. *Id.* at 324. In resisting a properly supported motion for summary judgment, the plaintiff has an affirmative

burden to designate specific facts creating a triable controversy. *Crossley v. Georgia-Pacific Corp.*, 355 F.3d 1112, 1113 (8th Cir.2004).

Patents are presumed to be valid. 35 U.S.C. § 282. Because of this presumption, a patent challenger must prove invalidity of a patent with clear and convincing evidence. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed.Cir.1991).

### Background

Astra owns patents claiming the pharmaceutically active compound metoprolol succinate and sustained release forms of that drug.

Metoprolol succinate is an active chemical compound used in the treatment of angina, hypertension, and congestive heart failure. Metoprolol succinate was invented at Plaintiff Aktiebolaget Hassle's facilities in Sweden. Astra manufactures and markets different dosages of metoprolol succinate in "extended release" <sup>FN2</sup> forms under the brand name Toprol-XL®. Astra holds two United States patents that claim "sustained release" formulations of metoprolol succinate and metoprolol succinate itself. These patents are United States Patent 5,001,161 (the '161 patent) and United States Patent 5,081,154 (the '154 patent) respectively. Astra asserts that its Toprol-XL® products are protected from infringement by these two patents.

FN2. Astra refers to its Toprol-XL® as an "extended release" drug in its Complaints against Defendants and in various documents that are part of the record in this case including its memorandum of law in support of its motion to dismiss Defendant KV Pharmaceutical's counterclaims (E.D. Mo. Cause No. 4:03CV592, Doc. # 31).

\*2 Defendants KV Pharmaceutical Company (KV), Andrx Pharmaceuticals, LLC and Andrx Corporation (Andrx), and Eon Labs, Inc. (Eon) <sup>FN3</sup> are pharmaceutical companies who seek to market their own extended release dosages of metoprolol succinate. KV, Andrx, and Eon separately filed Abbreviated New Drug Applications (an ANDA) with the United States Food & Drug Administration (the FDA) seeking ap-

proval of their extended release metoprolol succinate formulations as the first step to placing these drugs on the market. <sup>FN4</sup> In their respective ANDAs, Defendants asserted that their extended release metoprolol succinate formulations have the bioequivalence of Astra's Toprol-XL®. Astra claims that Defendants' metoprolol succinate drugs are merely generic versions of Toprol-XL® and infringe upon Astra's '161 and '154 patents.

FN3. KV, Andrx, and Eon are collectively referred to as "Defendants".

FN4. Defendants KV Pharmaceutical, Andrx, and Eon each seek to market 25, 50, 100, and 200 mg strengths of their respective metoprolol succinate formulations.

The Federal Food, Drug and Cosmetic Act, codified in pertinent part at 21 U.S.C. § 355 and 35 U.S.C. § 271, (Hatch-Waxman Act), creates a safe harbor from claims of patent infringement for certain activities directed to preparing an ANDA. However, the filing of an ANDA seeking FDA approval to enter the market with a generic drug before the expiration of patents claiming the drug or its use is considered an act of infringement. 21 U.S.C. § 271(e)(2). In such a circumstance the owner of the patent is authorized to bring suit for injunctive relief to prevent the commercial manufacture, use, offer to sell, or sale of the generic drug within the United States. 21 U.S.C. § 271(e)(4).

Because Defendants seek to market their extended release metoprolol succinate drugs before the expiration of Astra's '161 and '154 patents, Astra filed the present lawsuits seeking declaratory judgments of infringement. <sup>FN5</sup> Defendants have countered that their products do not infringe on Astra's patents and, in the alternative, that Astra's patents are invalid based on double patenting and inequitable conduct.

FN5. Astra brought suit against Defendant KV Pharmaceutical in this Court. Astra's suits against Defendants Andrx and Eon were filed in the United States District Court for the District of Delaware. These lawsuits were transferred to this Court by the United

States Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.

Specifically, Defendants assert that Astra's '161 and '154 patents are invalid for double patenting over earlier issued patents United States Patent 4,780,318 (the '318 patent) and United States Patent 4,957,745 (the '745 patent); and that the '154 patent is invalid for double patenting over the '161 patent. Defendants also argue that the '161 is invalid as anticipated by prior art under 35 U.S.C. § 102(b).

Additionally, Defendants assert that patents '161 and '154 are unenforceable based on inequitable conduct by Astra during their prosecution of the patents before the United States Patent and Trademark Office (USPTO). Defendants allege that named inventors of metoprolol succinate were intentionally misrepresented to the USPTO. Alternatively, Defendants assert that the three-year dispute between Astra and another drug company concerning inventorship of metoprolol succinate should have been disclosed to the USPTO.

#### Discussion

##### Invalidity based on double patenting

Defendants assert that Astra's '161 patent and '154 patents are invalid for obviousness-type double patenting. Obviousness-type double patenting, also referred to as nonstatutory double patenting (as distinguished from statutory double patenting under 35 U.S.C. § 101), is a judicially created doctrine that prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. *Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed.Cir.2003). This doctrine prevents patent applicants from extending their patent term for an invention beyond the statutory limits by claiming a mere obvious variant of the claims in a prior patent. *In re Emert*, 124 F.3d 1458, 1460 (Fed.Cir.1997).

\*3 The public policy behind this doctrine is to allow the public to freely use a patent upon its expiration. *In re Longi*, 759 F.2d 887, 892 (Fed.Cir.1985)(citing *In re Zickendraht*, 50 C.C.P.A. 1529, 319 F.2d 225, 232 (C.C.P.A.1963)(Rich, J. concurring)). Not only

should the invention claimed in the patent be available to the public upon its expiration "but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made...." *Id.*

In deciding whether a challenged patent is invalid for obviousness-type double patenting, a court must determine whether the claims of the challenged patent define an obvious variation of the claim in an earlier issued patent. *In re Emert*, 124 F.3d at 1461; *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1280 (Fed.Cir.1992)(double patenting principles extend to merely obvious variants of what has been patented). In order to compare claims of patents a court must construe what the claims are in each patent.

##### Claim construction

Defendants assert that Plaintiffs' '161 patent and '154 patent are invalid based on double patenting of claim 8 of the '318 patent. Defendants originally stated that they would apply Astra's construction of the '161 patent for purposes of their invalidity motion. That was before Defendants learned how Astra construed the term "sustained release" in the claim of that patent. The meaning of the term "sustained release" is disputed by the parties as is the construction of claim 8 of the '318 patent.

The United States Court of Appeals for the Federal Circuit has recently summarized and clarified the claim construction process in its decision in *Philips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005).<sup>FN6</sup> The "claims of a patent define the invention to which a patentee is entitled to the right to exclude." *Id.* at 1312. The claims are of primary importance in the effort to ascertain what it is that has been patented. *Id.* The words of a claim are generally given their ordinary and customary meaning. *Id.* The meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application. *Id.* at 1313. Importantly, the person of ordinary skill in the art is deemed to have read the claim term in the context of the claim as well as in the context of the entire patent, including the specification. *Id.*

FN6. I have excluded all internal quotations and citations in my citations to *Phillips*.

To determine the meaning of a term in a field of art, a court “looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean.” *Id.* at 1314. Those sources include intrinsic evidence, which encompasses the words of the claims themselves, the specification, and the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. *Id.*

\*4 Claims “must be read in view of the specification, of which they are a part.” *Id.* at 1315. The specification is the single best guide to the meaning of a disputed term. *Id.* It is entirely appropriate for a court, in the course of claim construction, to rely heavily on the written description in the specification for guidance as to the meaning of the claims. *Id.* at 1317.

Although a court may refer to extrinsic evidence in the form of expert and inventor testimony, dictionaries, and learned treatises, these sources are less significant than the intrinsic record in determining the legally operative meaning of claim language. *Id.* Conclusory or unsupported assertions by experts as to the definition of a claim term are not useful to a court performing a claim construction. A court should discount an expert's testimony regarding the meaning of a claim term if it is clearly at odds with the claim construction mandated by the intrinsic evidence of the claims themselves, the specification, and the prosecution history. *Id.* at 1318.

Defendants assert that claim 8 of the '318 patent is a specific extended release formulation of metoprolol succinate. They argue that the claim in the '161 patent for “sustained release” formulations of metoprolol succinate is merely an obvious variant of claim 8. The claim of the '154 patent simply claims the compound metoprolol succinate. Defendants contend that the claims in the '161 and '154 patents are a genus of the species identified in claim 8 of the '318 patent and are therefore void for double patenting.

To determine whether the '161 and the '154 patents

are invalid for double patenting over claim 8 of the '318 patent, the inventions claimed in each patent must first be construed. Because Defendants initially represented that the claim of the '161 patent was not in dispute a formal claims construction hearing was not held. As the positions of the parties crystalized during the summary judgment briefing it became clear that the parties did not agree to the construction of the term “sustained release” used in the '161 patent. The parties were clearly aware of this dispute and fully briefed and presented evidence in support of their construction of that term in their cross motions for summary judgment. I held a summary judgment hearing at which the parties presented intrinsic and extrinsic evidence in support of their construction of the claims in the '161, '154, and '318 patents. As a consequence, the parties placed into the record both intrinsic and extrinsic evidence in support of their claim construction positions.

#### The '318 patent

This patent concerns a drug formulation that allows the delivery of active drugs to the small intestine. Claim 8 of this patent includes a delivery formulation for metoprolol succinate. The “Abstract” of the '318 patent states that “[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastrointestinal duct....”

\*5 Under the heading “Background Of The Invention” the patent states that

[t]here exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect in the lower part of the gastrointestinal tract.

Under the heading “Object Of The Invention” the patent states that

[i]t has now surprisingly been shown possible to be able to solve the aforesaid problem by the present in-

vention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and/or which inner layer there is provided a second layer of at least one anionic polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

In the "Detailed Description Of The Invention" section the patent states that

[b]y means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution upon passage of the composition into the small intestine with its higher pH, a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant, pH-independent way, and thereby in a very reproducible way. (emphasis added)

Defendants argue that the '161 patent and the '154 patent are invalid for double patenting over claim 8 of the '318 patent. Because claim 8 depends from claim 7, which depends from claim 6, the starting point for claim construction is claim 6. Claim 6 is directed to oral controlled release pharmaceutical compositions with a core of the active drug, surrounded by a coating that is a diffusion membrane, and a second coating that resists dissolving in the pH of the stomach. It also specifies the materials used in each coating. Claim 6, 7 and 8 are as follows:

6. Oral pharmaceutical composition having an improved release therefrom of a therapeutically active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion

membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers of the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.

\*6 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range 1 to 8 which exceeds 0.5 to 1 g per 100 ml.

8. Pharmaceutical composition according to claim 7, wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalicylic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8.

Distilled to its essence, and pertinent to this lawsuit, claim 8 is directed to an oral pharmaceutical composition that has (i) a core that contains metoprolol succinate (or one of several other drugs), (ii) the core is surrounded by an inner coating that allows a controlled release of metoprolol succinate, and (iii) an outer coating that resists dissolving in the stomach with the goal of releasing the metoprolol succinate close to or within the colon.

The meaning of the term "improved release" in claim 6 can be interpreted from the specification which states that the goal of the invention is to release the active drug as close to the colon as possible. The specification also states that the diffuse membrane surrounding the core of metoprolol succinate acts to allow a "slow but controlled release" of the drug. Claim 8 patents a particular type of formulation to allow the slow and controlled release of metoprolol succinate in or near the colon.

#### The '161 patent

The '161 patent "Abstract" states that "[t]he present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical

preparations comprising this new compound.”

Under the patent heading “Technical Field” the patent states that “[t]he object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon, and particularly to such active compounds which are soluble in the pH range 1 to 8” (emphasis added).

Under the heading “Description of the Present Invention” the patent states that

“[t]his compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and 15 to 90% by weight of a water insoluble polymer selected from the group of quaternary ammonium substituted acrylic polymers.

...

When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered.

When administering, in order to achieve a steady blood plasma level of the therapeutically active compound, a split dose unit of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated. (emphasis added)

\*7 The sole claim of the '161 patent is “[a]<sup>FN7</sup> sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier.”

FN7. The term “sustained release” was recently repositioned in the “claim” section of the '161 patent by the USPTO. The USPTO amended the patent to have the term follow the initial “a” in this claim sentence from following the second “a” as originally filed. The amendment was made at Astra's request.

For the purposes of their motion for summary judgment based on invalidity, Defendants agreed to the revised wording of the sole claim of the '161 patent. FN8 Astra broadly construes the definitions of the terms used in this claim. Defendants disagree with Astra's definition of the term “sustained release.” Astra contends that sustained release means dosage forms which, “upon ingestion, released active to achieve desired blood plasma levels and maintained relatively steady blood plasma levels for an extended period of time.” (Pls.' Memo. in Opp. at 23.) Defendants assert that the term sustained release, as used in the mid 1980s by a person of ordinary skill in the art when this patent application was filed, was deemed interchangeable with the terms “extended release” and “controlled release.”

FN8. The USPTO had not yet approved Astra's request to change the location in the claim of the term sustained release when the briefing of this motion was filed.

The term “sustained release” does not appear in the specification of the '161 patent. The invention described by the specification is a core of “active,” metoprolol succinate, coated by an anionic polymer with the goal of releasing metoprolol succinate close to or within the colon. The specification also states that uncoated particles/granules of metoprolol succinate may be combined with metoprolol succinate “provided with a coating according to the *present invention*” (emphasis added) to achieve a steady blood plasma level of metoprolol succinate. This last specification clearly regards the invention as the coated metoprolol succinate. It does not state that the invention is the coated metoprolol succinate combined with uncoated metoprolol succinate to achieve a steady blood plasma level. Astra contends that the invention claimed in the '161 patent is this latter construction which Astra labels “sustained release.”

In support of its construction of the term “sustained release,” Astra offers the affidavit of its expert Gerald S. Brenner. In paragraph 35 of his affidavit, Brenner states that one skilled in the art in the mid 1980s would “generally have considered a sustained release dosage form one that initially (upon ingestion) releases active to achieve desired blood plasma levels

and maintains relatively steady blood plasma levels of the active for an extended period of time.” (Pls.’ Opp’n Summ. J. Ex. A) In support of this statement Brenner’s affidavit refers to three documents without identifying them or vouching for their use by experts in his field as reference tools. The three documents are excerpts from what appear to be pharmaceutical texts. I presume that these are treatises used in the field of pharmacology.

The first excerpt is from Robert E. Notari, *Biopharmaceuticals and Clinical Pharmacokinetics, An Introduction* (Marcel Dekker, Inc., 3rd ed.1980). Notari discusses the term sustained release and states that \*8 “[g]eneral terms such as timed release, time release, extended action, or long-acting may or may not be meant to indicate that the formulation is a sustained release preparation. Unfortunately, there are no standard definitions or classifications. The following distinction will be used as a starting point, and later more precise terminology and definitions will be given to sustained release dosage forms.”

*Id.* at 152. Notari then goes on to define the meaning of the terms “repeat-action tablets,” “sustained release dosage forms,” and “prolonged-action preparations.” He defines sustained action dosage forms as providing an “initial therapeutic dose that is available upon administration of the product followed by a gradual release of medication over a prolonged period of time.” *Id.* He states that prolonged-action preparations provide the slow release of a drug and may differ from sustained release dosage only in that no initial dose is included in the prolonged-action formulation. *Id.*

Although Notari’s definition of sustained release at first blush appears to support Astra’s definition, Notari specifically notes that there were no standard definitions or classifications of dosage terms including sustained release. Rather, Notari’s article was his attempt to create definitions that would presumably be adopted at some time in the future by a person skilled in the art. As a result, Notari’s text does not support Astra’s contention that sustained release had a specific meaning to one skilled in the art as of the effective date of the patent application. Instead, Notari’s article establishes the opposite position; that in the

mid 1980s there was no consistent interpretation of the term sustained release.

The second document relied on by Brenner is equivocal in supporting his definition of sustained release. That excerpt is from Howard C. Ansel, *Introduction to Pharmaceutical Dosage Forms*, (Lea & Febiger 1969). Ansel states that [s]ome solid dosage forms are designed to release their medication to the body for absorption rapidly and completely; other products may be designed to release the drug slowly for more prolonged drug release and sustained drug action. The latter type of dosage form is commonly referred to by a designation such as a *sustained-action*, *prolonged-action*, *sustained-release*, *prolonged-release*, *timed-release*, *extended-action*, or *extended-release* tablet or capsule.

*Id.* at 274. Ansel then states that “most” sustained-action dosages are designed so that a single dosage provides the “immediate release of an amount of the drug that promptly produces the desired therapeutic effect and gradual and continual release of other amounts of drug to maintain this level of effect over an extended period....” *Id.* Ansel uses the term “most” which indicates that his definition is not universal to all sustained-action dosages. As quoted above, Ansel notes the term sustained release was also referred to as extended release, timed release, extended action among other terms. These terms interchangeably referred to dosages, which Notari highlighted in his treatise published ten years after Ansel’s, that may not be an indication of sustained release as defined by Ansel because there were still no standard definitions of any of these terms in 1980.

\*9 Finally, the third treatise Brenner relies on for his definition of sustained release is *Remington’s Pharmaceutical Sciences* (Mack Pub. Co., Arthur Osol ed.1980). That treatise states that long-acting oral products have been described by a variety of terms. *Id.* at 1596. The treatise then proposes classifying long-acting products into the following three types: sustained release, prolonged release, and repeat action. *Id.* This treatise does not state that sustained release is defined similarly by those skilled in the art. To the contrary, it offers a definition that may be ad-

opted at some time in the future by those skilled in the art.

The three treatises relied on by Astra and its expert Brenner are consistent only in that none of the treatises state that sustained release had a uniform definition used by those skilled in the art in the mid 1980s. At best these treatises offer definitions which may or may not have been uniformly adopted. What is clear is that sustained, extended, or timed release dosages were deemed to be dosages that released more slowly over time than immediate release dosages.

The prosecution history of the '161 patent also demonstrates that Astra's own definition of sustained release was not consistently maintained during the prosecution of the patent. As previously noted, the term sustained release does not appear in the specification of the patent. When originally filed, the claims of the patent were directed to metoprolol succinate and a "pharmaceutical composition, characterized in that the active compound is metoprolol succinate." (Defs.' Ex. Q at 145) The USPTO examiner rejected these claims as obvious over prior art. *Id.* at 167-169. Hassle (Astra) responded to the rejection with a declaration of Dr. John Anders Sandberg. Hassle represented that Sandberg's declaration showed that metoprolol succinate was "useful as a sustained release form of metoprolol." *Id.* at 174. Sandberg's declaration interchangeably used the terms extended release, sustained release, and controlled release in supporting the selection of metoprolol succinate. *Id.* at 181, 184, and 189. The examiner agreed to issue the '161 patent if the term sustained release was inserted into the claim. In his deposition for this case, Sandberg stated that he thought that controlled release, sustained release, and extended release dosages were essentially the same. (Defs.' Ex. V at 413) One of the named inventors of the '161 and '154 patents, Curt Appelgren, stated in his deposition that in 1983 the terms controlled release, extended release, and sustained release were use interchangeably. The other named inventor of the "161 and '154 patents, Eva Christina Eskilsson, stated in her deposition that sustained release could be the same as extended release, which could be a dosage form completely releasing an active drug from "one to many hours." (Defs.' Ex. T at 345)

Defendants have placed more treatises and articles into the record that state that sustained release, prolonged action, controlled release, extended action, and time release were all used interchangeably to describe preparations that release a drug over an extended period of time. (Defs.' Exs. AB, AC, and AD)

\*10 Astra itself uses the term "extended release" in their Complaints and various pleadings when they describe their drug Toprol-XL® which is the subject of this infringement action.

Based on the lack of a definition of sustained release in the '161 patent, the specification's statement that the "object of the present invention is to obtain a therapeutically active compound *intended to be released close to or within the colon*" and the extrinsic evidence offered by the parties, I conclude that sustained release simply refers to a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon. Astra's definition requiring an immediate release is not supported by the specification. Astra's extrinsic evidence in the form of Brenner's affidavit "is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" and is discounted. *Phillips*, 425 F.3d 1318. In addition, Brenner's definition is not even supported by the treatises he relies on in support of his position.

The specification itself states that if a steady blood plasma level of the therapeutically active compound is desired, an optional formulation of uncoated metoprolol succinate can be combined with metoprolol succinate with a coating according to the present invention. That statement, read in context of the entire patent, indicates that the invention of the '161 patent is a coated forms of metoprolol succinate that provides for a controlled or extended release of the drug; it is not a pharmaceutical composition that includes an immediate release of metoprolol succinate as Astra would define the term sustained release.

#### The '154 patent

The only claim in the '154 patent is "metoprolol suc-

ciate.” The invention is the composition itself.

#### Comparing the claims

Claim 8 of the '318 patent is directed to a specific type of controlled release formulation of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon).

The claim of the '161 patent is directed to coated forms of metoprolol succinate that are designed to have a controlled release of the metoprolol succinate (the active) near or in the colon. The claim does not limit the method or structure by which controlled release is achieved. It is broadly directed to formulations that would provide a controlled release of metoprolol succinate near or in the colon.

Defendants argue that claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the '161 patent is a broad claim to any controlled release formulations of metoprolol succinate. Defendants assert that the relationship between the claim 8 of the '318 patent and the claim of the '161 patent is that of “species and genus,” that is, the former discloses a specific embodiment within the latter's general scope.

\*11 A species/genus relationship is a form of double patenting wherein the second broader claim is deemed invalid because it is anticipated by, and therefore not patently distinct from, an earlier species claim. See *In re Goodman*, 11 F.3d 1046, 1053 (Fed.Cir.1993); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed.Cir.2001); *Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC*, 349 F.3d 1373, 1383 (Fed.Cir.2003).

Astra asserts that the relationship between claim 8 of the '318 patent and the claims of the '161 patent and the '154 patent should be viewed as that of combination/element which does not implicate the doctrine of double patenting. See *In re Allen*, 52 C.C.P.A. 1315, 343 F.2d 482, 486 (C.C.P.A.1965); *In re Heinle*, 52 C.C.P.A. 1164, 342 F.2d 1001 (C.C.P.A.1965). Astra

contends that the claims of the '161 patent and the '154 patent are independent elements of the combination claim of claim 8 of the '318 patent. Astra argues that metoprolol succinate was not a necessary element to the combination claim 8 of the '318 patent and that metoprolol succinate has utility by itself or in other combinations. As a result, Astra argues, its claims concerning metoprolol succinate cannot be invalidated for double patenting.

However, “ ‘[i]n situations in which an element or subcombination issues after the combination, the matter should be analyzed as one of a generic claim issuing after a later filed specific or improvement claim.’ ” *In re Emert*, 124 F.3d 1458, 1462 (Fed.Cir.1997)(quoting 3 Donald S. Chisum, *Chisum on Patents* § 9.03[2][b][iii] ).

That is the situation in the present case. Even if the '161 claim and the '154 claims are classified as elements, they issued after the combination claim of claim 8 of the '318 patent issued. It is therefore appropriate to analyze these claims as a species/genus relationship. I find that claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the '161 patent is a broad generalized claim to controlled release formulations of metoprolol succinate. Because the earlier issued claim 8 of the '318 patent is a species of the later issued genus claim of the '161 patent, the '161 claim is invalid for obviousness type double patenting.

The sole claim of the '154 patent is “metoprolol succinate.” Such a claim encompasses any formulation that uses this chemical composition without limitation. Claim 8 of the '318 patent is directed to certain pharmaceutical compositions containing metoprolol succinate. The '154 patent broadly claims any pharmaceutical compositions containing metoprolol succinate. The relationship between these claims is that of species/genus. The '154 patent is a genus of the species claimed in the '318 patent. Consequently, the claim of the '154 patent is anticipated by claim 8 of the '318 patent and is void for double patenting because it is not patently distinct from claim 8 of the '318 patent.

Not Reported in F.Supp.2d

Page 10

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

\*12 If the '161 and '154 patents were valid, they would prevent the public from using the earlier issued invention of claim 8 of the '318 patent upon its expiration because they completely encompass claim 8 as to metoprolol succinate. Such a result would defeat the public policy behind the double patenting doctrine which is to allow the public to freely use a patent upon its expiration.

As a result, I find by clear and convincing evidence that the '161 patent and the '154 patent are invalid on the basis of double patenting over claim 8 of the '318 patent.

#### Terminal disclaimers

Defendants also asserted that the '161 and '154 patents are invalid for double patenting over earlier issued patent United States Patent 4,957,745 (the '745 patent); and that the '154 patent is invalid for double patenting over the '161 patent.

Claim 7 of the '745 patent is another controlled release formulation of metoprolol succinate. It claims a formulation of metoprolol succinate wherein the metoprolol is released through a coating over a period of at least fifteen hours. Base on the same analysis applied to claim 8 of the '318 patent, I find that claim 7 of the '745 patent is a species of the later filed genus in the claims of the '161 and '154 patents. The claim of the '161 patent and '154 patent would be invalid for double patenting over claim 7 of the '745 patent if not for the question of terminal disclaimers.

By the same analysis the claim of the '154 patent would also be invalid for double patenting over the '161 patent.

However, Astra filed terminal disclaimers under 35 U.S.C. § 253 as to the '161 patent and the '154 so that they expire at the same time that the '745 patent expires.<sup>FN9</sup> Astra contends that these terminal disclaimers cure any double patenting issues that may have arose between the '154 patent and the '161 patent and those two patents and the '745 patent.

FN9. Defendants state that the expiration date of the '745 patent is September 18, 2007.

Defendants argue that the terminal disclaimers should have been made while the '161 and '154 patents were being prosecuted. Defendants assert that Astra's disclaimers, filed years after the patents have issued, are ineffective based on public policy. Defendants contend that a listing of pharmaceutical patents and their expiration dates in the Orange Book<sup>FN10</sup> deters others from competing with the patent holder on those patents. Defendants assert that allowing a patent holder to avoid a double patenting litigation by filing a terminal disclaimer years after a patent was issued gives the patentee an unfair advantage by suppressing competition.

FN10. The United States Food & Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, commonly referred to as "the Orange Book," is a register that provides notice of patents covering name brand drugs.

The terminal disclaimer statute does not set a time limit to file a disclaimer. The language of the statute clearly contemplates that a disclaimer can be filed by a patentee regarding a patent that has already issued. 35 U.S.C. § 253 ("patentee ... may disclaim ... the entire term, or any terminal part of the term, of the patent granted...."). The United States Court of Appeals for the Federal Circuit has recently confirmed that a terminal disclaimer may be filed after a patent is issued. *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 2005 WL 3468126, at \*5 (Fed.Cir. December 20, 2005). The *Perricone* opinion also states that a "terminal disclaimer can indeed supplant a finding of invalidity for double patenting." *Id.* The opinion strongly infers that a terminal disclaimer filed years after a judicial finding of invalidity can reinstate the validity of the patent. *Id.* The court in *Perricone* did not raise concerns that equity or public policy should prevent terminal disclaimers from being effective if filed years after a patent has issued.

\*13 Based on the language of the terminal disclaimer statute and the opinion in *Perricone*, I find that Astra's terminal disclaimers of the '161 patent and the '154 patent effectively avoids a finding of double patenting of those patents over the '745 patent and the '154 patent over the '161 patent.

Not Reported in F.Supp.2d

Page 11

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

The '161 patent not entitled to priority and is therefore invalid as anticipated

Defendants also argue that the '161 invalid as anticipated by prior art under 35 U.S.C. § 102(b). Defendants contend that the '161 patent was not entitled to priority to the '318 patent application. Through the use of priority, its possible for a patentee to avoid the consequences of any prior art which existed before his present patent application was filed. That is because a priority entitles the patentee to adopt the earlier filing date of a related patent application.

The '161 patent issued from a continuation-in-part patent application filed in March 1988. The application claimed priority to the United States application for the '318 patent which was filed on January 10, 1985 (the '318 patent application in turn claimed priority to the Swedish patent application (SE 8400085) filed on January 10, 1984). If the '161 patent is not entitled to priority to the '318 patent application, its effective filing date would be March 1988. Any references with sustained release metoprolol succinate formulations that existed before March 1988 might qualify as prior art that anticipates the '161 patent.

Patent law allows a patent applicant to claim priority to an earlier filed patent application. 35 U.S.C. § 120. For a claim in a later-filed application to be entitled to the filing date of an earlier application under section 120, the earlier application must comply with the written description requirement of paragraph one of 35 U.S.C. § 112. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed.Cir.1998).

Paragraph 1 of section 112 requires that the specification "contain a written description of the invention, and of the manner and process of making and using it." To meet this requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed." *Id.* (citations omitted.) A disclosure in a parent application that "merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations." *Id.* (citation omitted).

As previously discussed, the '318 patent is directed to, in pertinent part, a specific type of controlled release formulation of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two specified coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon). The specification of the '318 patent is limited to this dual-coating system. The specification does not describe other systems for the sustained release of metoprolol succinate.

\*14 The '161 patent broadly claims sustained release formulations of metoprolol succinate with little, if any, limitation. The specification of the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161 patent at the time the '318 application was filed. To be entitled to a priority the disclosure in the '318 patent must describe the '161 patent invention with all its limitations. The '318 patent does not contain this information.

Because the specification of the '318 patent does not meet the written description requirement of invention of the '161 patent, the '161 patent is not entitled to priority to the '318 patent. As a result, the effective filing date of the '161 patent is March 25, 1988.

Swedish patent application SE 8400085 is the parent of the '318 patent and the grandparent of the '161 patent. The Swedish application published on July 17, 1985. The Swedish application discloses, among other things, the species of sustained release metoprolol succinate that becomes claim 8 of the '318 patent. The disclosure of the species in Swedish patent anticipates the genus of sustained release metoprolol succinate which is the invention of the '161 patent. Because the species in the Swedish patent application was published (July 1985) more than one year before the '161 patent application was filed (March 1988), the '161 patent is invalid under 35 U.S.C. § 102(b) (a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States).

Similarly, as already discussed, the '745 patent and the '161 patent have a species/genus relationship. The '745 patent was filed in September 1986. An issued United States patent qualifies as prior art as of its filing date. 35 U.S.C. § 102(e). Because the '745 patent application was filed more than one year before the '161 patent application, the '745 patent is prior art which anticipates the '161 patent and renders it invalid.

As a result, I find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent and that the '161 patent is invalid as anticipated by the publication of the Swedish patent application and the filing of the '745 patent application.

#### Unenforceability based on inequitable conduct

For more than three years, from October 1985 through the late fall of 1988, Astra and a competitor named Lejus Medical contested the issue of who invented metoprolol succinate. This dispute was uncovered during discovery in this lawsuit. Astra never revealed its inventorship dispute with Lejus to the USPTO during the prosecution of the patents in suit. Astra's failure to disclose this long-running inventorship dispute is one basis for Defendants' motion for summary judgment for inequitable conduct.

Defendants also assert that Astra intentionally did not name the correct inventors in Astra's prosecution of the patents in suit. Curt Appelgren and Eva Eskilsson are the two named inventors of the '161 patent and the '154 patent. Defendants assert that Appelgren and Eskilsson are not the inventors of the patents in suit and that listing them as the named inventors on the patent applications was a material misrepresentation to the USPTO.

\*15 Defendants contend that Astra's naming the wrong inventors on the patents and Astra's failure to disclose to the USPTO the inventorship dispute each independently constitute an act of inequitable conduct which render the patents in suit unenforceable.

Astra denies these allegations. It asserts that it named the correct inventors of the '161 and the '154 patents. Astra also contends that, through its United States patent counsel, it fully satisfied its duties of candor

and disclosure to the USPTO during the prosecution of these patents.

#### Standard regarding inequitable conduct

"Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed.Cir.2000) (citation omitted). Because the defense of inequitable conduct is entirely equitable in nature, it is an issue for the court and not a jury to decide. *Id.*

To determine whether inequitable conduct exists requires the trial court to determine whether the conduct meets a threshold level of materiality and whether the evidence shows a threshold level of intent to mislead the USPTO. *Id.* at 1318-19. Materiality and intent must be established with clear and convincing evidence. *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1234 (Fed.Cir.2005). Once threshold levels are established, the trial court is required to weigh materiality and intent. *PerSeptive Biosystems, Inc.*, 225 F.3d 1319. "The more material the conduct, the less evidence of intent will be required in order to find that inequitable conduct has occurred." *Id.* (citation omitted). In "the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Bruno Indep. Living Aids, Inc. v. Acom Mobility Services, Ltd.*, 394 F.3d 1348, 1354 (Fed.Cir.2005). After weighing materiality and intent, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable. *PerSeptive Biosystems, Inc.*, 225 F.3d 1319. Defendants assert that Astra engaged in inequitable conduct towards the USPTO by (1) misrepresenting the inventors of the '161 patent and the '154 patent, and (2) failing to disclose the inventorship dispute between Astra<sup>FN11</sup> and its competitor Lejus.<sup>FN12</sup> Defendants argue that this information about inventorship was material to the prosecution of the patents.

FN11. This dispute was actually between Hassle and Lejus. Hassle is now part of As-

Not Reported in F.Supp.2d

Page 13

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

traZeneca and I will use the term "Astra" to refer to both Hassle and Astra as the parties have done in their briefs.

FN12. Defendants' allegations of inequitable conduct arose from information uncovered in discovery concerning who originally conceived and synthesized metoprolol succinate and a dispute over inventorship of that compound.

Information is material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. *Id.* at 1322 (quotations and citations omitted). Because it is a critical requirement for obtaining a patent, the issue of inventorship is highly material in the patent prosecution process. *Id.* at 1321; 35 U.S.C. § 102(f) (A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented.). In turn, conduct that would mislead the USPTO as to the identity of the true inventors of a patent or conduct that fails to disclose information about a dispute concerning inventorship would be highly material to the question of inequitable conduct because of the patentee's duty of candor and disclosure. *See* 37 C.F.R. § 1.56 ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

\*16 Disputes concerning inventorship are material information that need to be disclosed. *PerSeptive Biosystems, Inc.*, 225 F.3d at 1321 (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004). Because conduct concerning inventorship is so highly material, less evidence of intent is required in order to find that inequitable conduct has occurred.

#### *Inventorship of metoprolol succinate*

The compound metoprolol was invented in the 1960's by Hassle, at the time, a Swedish pharmaceutical research and development company located in Mölndal, Sweden. Metoprolol was discovered to be

very useful in treating heart disease. Astra (Hassle) began work to develop a commercial metoprolol product. Astra investigated various salts of metoprolol to be used in a drug formulation. It is undisputed that in 1971, an Astra chemist named Toivo Nitenberg synthesized metoprolol succinate as well as the tartrate and sulfate salts of metoprolol. Nitenberg recorded the synthesis of these salts in his lab notebook. The tartrate salt was chosen for commercialization and became Astra's product known as Lopressor.

In the 1980's Astra perceived a need for a once-daily dosing formulation of metoprolol. Because this goal could not be effectively achieved with metoprolol tartrate, Astra formed a research group to develop an extended release form of metoprolol. Curt Appelgren and Eva Eskilsson were part of that group.

In 1982, Appelgren and his colleague Ulf Jonsson went to Astra's facility in Södertälje, Sweden and asked chemists there to form some metoprolol salts with a lower solubility than the tartrate for evaluation as an extended release form of metoprolol. They met with Urban Stenhede, a chemist and head of the research department. Jonsson (Astra's Rule 30(b)(6) witness) <sup>FN13</sup> testified in his deposition that he and Appelgren asked Stenhede to make some salts of metoprolol, other than the tartrate, with lower solubility. Jonsson testified that there was no specific request made to Stenhede to make metoprolol succinate.

FN13. A Rule 30(b)(6) witness must be able to give binding answers on a corporation's behalf. *Reilly v. Natwest Markets Group Inc.*, 181 F.3d 253, 268 (2d Cir.1999).

In Appelgren's deposition, when asked about his and Jonsson's meeting with Stenhede, Appelgren could not recall specific details of the meeting. He did not testify that he gave Stenhede a list of salts to make, including metoprolol succinate. But in his later filed declaration submitted in opposition to summary judgment on the issue of inequitable conduct, dated ten months after his deposition, Appelgren states that he did give Stenhede a list of salts to make that included metoprolol succinate. No such list was produced in

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 14

discovery.

Stenhede, in turn asked chemist Lars Lilljequist to form salts of metoprolol with a lower solubility than the tartrate salt. Lilljequist is the person who actually synthesized metoprolol succinate. In his deposition, Lilljequist did not recall who suggested which salts of metoprolol to form nor could he recall if he was given a list of salts to make. Yet he clearly testified that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). (Def. Andrx's Memo in Reply Ex. 3 at 87) But in his later filed declaration submitted in opposition to summary judgment, dated seven months after his deposition, Lilljequist states that he received a list of salts to make that included metoprolol succinate.

\*17 In their depositions, both Appelgren and Eskilsson testified that they were unaware that Nitenberg had formed metoprolol succinate at their company in 1971. They testified that they had never seen his lab book entry showing the formation of that salt. In her deposition, Eskilsson states that she did not recall asking anyone to make metoprolol succinate and that she never made metoprolol succinate. She also did not recall why she was a named inventor of metoprolol succinate in United States Patent Application No. 172,897 (the application that became the '161 patent and through a continuation the '154 patent). (Defs. Memo in Supp. Ex. 16 at 496) However, in her later filed declaration submitted in opposition to summary judgment, dated ten months after her deposition, she asserts that she did invent metoprolol succinate and the basis for that belief.

In December 1982, Appelgren left Astra to found Lejus Medical, a Swedish pharmaceutical research and development company. A few months later Eskilsson also became employed at Lejus.

On January 10, 1984, Lejus filed a patent application (SE 8400085) with the Swedish Patent Office. That application published as EP 148811 on July 17, 1985. The Swedish patent application was for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate. Appelgren and Eskilsson are listed as the named inventors.

On January 1, 1985, the same application was filed in the United States as United States Application No. 690,197 which issued on October 25, 1988, as the '318 patent discussed above. The '318 patent is the parent and grandparent of the patents in suit, the 161 patent and the '154 patent, respectively.

When the Swedish patent application published in July 1985 it was noticed by Astra. Astra believed that metoprolol succinate had been invented by its employee Toivo Nitenberg and that extended release dosage formulations of metoprolol succinate were also Astra's invention. In an internal memorandum dated September 19, 1985, Astra's in-house counsel, Bengt Wurm, stated that it appeared Lejus was trying to appropriate Astra's claim to metoprolol succinate and extended release dosage formulations of metoprolol succinate. Wurm warned that "the important principle is that the use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty reference with respect to later applications that concern preparations containing substances such as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10) In other words, the publication could constitute potentially invalidating prior art of any subsequent Astra application seeking to patent metoprolol succinate.

On October 21, 1985, Astra filed an action in the Swedish Patent Office to transfer the metoprolol succinate inventions of the Lejus' Swedish application to Astra. Astra's petition, signed by Astra's in house counsel Wurm, asserted that metoprolol succinate had *not* been invented by Appelgren or Eskilsson, but rather it had been invented by an Astra chemist named Toivo Nitenberg. (Defs.' Memo in Supp. Ex. 11) In 1985, Astra's petition at the Swedish Patent Office noted that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." *Id.* In making this assertion, Wurm relied on information from John Sjogren, the head of the formulation department at Astra. (Defs.' Memo in Supp. Ex. 12)

\*18 Wurm advised Astra, however, that seeking transfer of the metoprolol succinate invention under Swedish patent law could be time consuming, ex-

# **Exhibit 46**

## **Part II**

Not Reported in F.Supp.2d

Page 15

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

pensive, uncertain and of questionable future value because the Lejus publication could be cited as prior art to "later applications that concern preparations containing substances such as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10)

As an alternative to pursuing its action in the Swedish Patent Office, Astra attempted to reach an accommodation with Lejus. In the fall of 1985, Astra approached Lejus and asserted that metoprolol succinate (and its pharmaceutical compositions) had not been invented by Appelgren and Eskilsson but had, in fact, been invented by Nitenberg at Astra. Lejus did not dispute Astra's claim. Lejus agreed to file new patent applications on the metoprolol succinate inventions (to be carved from the 1984 Swedish patent application and each of its foreign counterparts, e.g. the '318 patent application) and then assign these applications to Astra. In exchange Astra agreed to withdraw its ownership claim with the Swedish Patent Office claiming that Toivo Nitenberg was the actual and sole inventor of metoprolol succinate. In April 1986, Astra and Lejus entered a written agreement incorporating these terms.

Prior to the signing of the formal agreement, Lejus had already filed, in January 1986, the required new application in Sweden on the metoprolol succinate inventions (Swedish Patent Application No. 8600202-9).

Wurm was succeeded by Rune Nasman as Astra's in-house attorney. On February 12, 1988, almost two years after Astra and Lejus entered the agreement regarding the metoprolol inventions, Nasman wrote two letters to Lejus' outside patent agent Ulf Inger still asserting that Toivo Nitenberg was the sole inventor of metoprolol succinate. In the first letter, entitled "Metoprolol succinate-divided application in the United States," Nasman reasserts Astra's position that Toivo Nitenberg was *the* inventor of metoprolol succinate ("As we understand it, and as was stated in the objection to the Swedish Patent Office, *the inventor is Toivo Nitenberg*, employed by Hassle.") (emphasis added) (Defs.' Memo in Supp. Ex. 23)

In the second letter of February 12th, entitled "Swedish patent application 8600202-9, AB Hassle,"

Nasman tells Inger that Toivo Nitenberg should be named as the inventor of metoprolol succinate. He states that Appelgren and Eskilsson can remain as co-inventors with Nitenberg because the application also "pertains to a pharmaceutical composition, and Appelgren and Eskilsson appear to have invented a special form of pharmaceutical composition under this patent claim." (Defs.' Memo in Supp. Ex. 24)

On March 25, 1988, a little over a month after Nasman sent these letters, Lejus filed United States Patent Application No. 172,897 (which became the '161 patent). This application was the United States counterpart to the Swedish Application No. 8600202-9 discussed in Nasman's letters. Like its Swedish counterpart, the United States application claimed: 1) metoprolol succinate and 2) "a pharmaceutical composition, characterized in that the active compound is metoprolol succinate." The named inventors were Appelgren and Eskilsson. The application was filed as a continuation-in-part of United States Patent Application No. 690,197 (which became the '318 patent). By filing the application as a continuation-in-part of the '197 application and naming the same inventors, the '897 application was entitled to priority to the earlier filing date of the '197 application, January 10, 1985. A material benefit of the January 10, 1985, filing date would be to avoid a potential hurdle of prior art revealed in the publication of EP 148811 on July 17, 1985. The issue of a potential prior art problem had been specifically identified by Wurm two and a half years earlier in his September 19, 1985 internal memorandum at Astra.

\*19 On May 31, 1988, *two months after* the '897 application is filed in the United States, Nasman writes another letter to Inger stating that he looks forward to Lejus' assignment of the European and United States metoprolol succinate patent applications to Astra per their agreement. Nasman again reemphasizes Astra's desire for Nitenberg to be named as the inventor of metoprolol succinate because "[t]here can be no doubt that the invention as specified in claim 1 was made in connection with Toivo Nitenberg's synthesis of the salt." (emphasis added) (Defs. Memo in Supp. Ex. 25.) He further states that Appelgren's and Eskilsson's roles as inventors to claim 2 (a generally specified pharmaceutical composition of metoprolol suc-

Not Reported in F.Supp.2d

Page 16

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

ciate) "should be limited to the special form of pharmaceutical composition that is specified in Lejus' original application." *Id.*

In late 1988, the prosecution of the '897 patent application was transferred from Lejus' United States patent counsel to Astra's United States patent counsel, Edward Filardi. On January 9, 1989, Nasman wrote to Filardi for advice with respect to inventorship, which Nasman described as an "*open question*" with respect to the '897 application. (emphasis added) (Defs. Memo in Supp. Ex. 27) His letter states, in pertinent part, as follows:

The background, to my knowledge, is that metoprolol [succinate] was first synthesized on September 6, 1971 by the Hassle chemist Toivo Nitenberg. I enclose a copy of Mr. Nittenberg's lab protocol of the synthesis (in Swedish).

In 1985 we discovered that a Swedish patent application (no. 8400085-0) filed by Lejus Medical AB and naming two former Hassle employees, Kurt Appelgren and Christina Eskilsson, mentioned metoprolol succinate as an active component for an invented pharmaceutical composition. Hassle took action against Lejus in the Swedish patent office asserting rights under the patent based on Hassle's view that the invention of metoprolol succinate was made by Mr. Nitenberg and that Appelgren and Eskilsson had used secret Hassle know-how in making reference to metoprolol succinate in the Lejus patent application. After negotiations between the parties a settlement was reached stipulating inter alia that Lejus w[as] to divide out the parts of their applications pertaining to metoprolol succinate into separate applications, which were to be assigned to Hassle, and that Hassle w[as] to withdraw all actions for rights under the patents.

As I understand it, there remains an open question who is the proper inventor of the invention claimed in the instant U.S. patent application [the '161 patent application], and your advice on this would be appreciated. I may inform you that we have [u]nofficially proposed to Lejus, via Ulf Inger, to add Mr. Nitenberg as an inventor in the Swedish counterpart to the instant application, but so far Lejus h[as] not agreed to do this.

*Id.* The letter does not inform Filardi that Astra also

sought to have Lejus name Nitenberg as the inventor of metoprolol succinate in the United States patent applications. *See* Nasman's letters to Inger above.

\*20 On January 10, 1989, Filardi sent a letter to Nasman stating that he discussed the inventorship issue with Peder Berntsson and Gerhard Miksche but had several questions that could not be resolved. (Defs.' Memo in Supp. Ex. 28) Filardi proposed that he call Nasman the next day, January 11, 1989, with Berntsson and Miksche participating in the call, to discuss the issue further.

The call was made on January 11th. Nasman writes a letter to Filardi the same day referring to patent application '897 (and two other applications). (Defs.' Memo in Supp. Ex. 29) The letter refers to "the very useful telephone conversation today with you." Berntsson, Miksche, and a Margareta Linderöth also participated in the call. The issue of inventorship is not mentioned in the letter. This letter ends the paper trail of how the open question of inventorship was addressed by Nasman and Filardi.

On April 19, 2005, Filardi was deposed for this lawsuit. He was asked if he reviewed documents in preparation of his deposition. He said that he had and that some of the documents helped refresh his recollection of what occurred during the prosecution of the patent applications as issue. He testified that he could not recall anything that was said during the January 11, 1989 telephone call with Nasman. He specifically states that he could not recall anything that was said about the inventorship of the '897 application. He could not recall if he did, or did not, render any opinion regarding inventorship of the '897 application during the phone call. Aside from Nasman's January 11th letter, the record does not contain any other contemporaneous evidence of Filardi's advice regarding the "open question" of inventorship raised by Nasman.

Astra states that Peder Berntsson was Nitenberg's boss at Astra and was very familiar with Nitenberg's synthesis of metoprolol succinate. Berntsson met with Filardi on January 10th and was involved in the conversations between Nasman and Filardi on January 11th. However, there is no evidence in the record

Not Reported in F.Supp.2d

Page 17

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

of what Berntsson specifically discussed with Filardi on January 10th and 11th. Berntsson has submitted a declaration in opposition to summary judgment on the issue of inequitable conduct. Berntsson's declaration does not mention these meetings with Filardi. Nor does it reveal that he ever provided any information to Filardi or Nasman about inventorship of metoprolol succinate.

According to Astra's memorandum in opposition to summary judgment:

During the January 11 telephone call, Filardi advised Nasman with the requested legal advice on inventorship. In particular, Filardi advised Nasman that, in his opinion, Nitenberg was not an inventor or co-inventor of metoprolol succinate, that there was no doubt about it, that none of the information set forth in Nasman's letter to Filardi was material, and that, therefore, the information did not need to be disclosed to the USPTO.

(Pls.' Memo in Opp. at 20) Astra cites to the declarations of Nasman and Filardi in support of this assertion.

\*21 Astra's assertion of what was discussed during the January 11th phone call is not supported by the record in this case. In his deposition, Filardi stated that he had no recollection of what was discussed about inventorship in his conversation with Nasman on January 11th. Filardi made a declaration, however, three months after his deposition which has been submitted in opposition to summary judgment. In pertinent part of his declaration concerning the inventorship issue, Filardi does not state that he recalls what happened but rather what is "clear" to him based on review of some documents. In other words, Filardi still does not recall the relevant conversation. Filardi never declares what he actually knew, considered or said. His declaration reflects that he is surmising or guessing at what he must have told Nasman.

For example he states that based on the contemporaneous documents:

*it is clear* that I considered the five items of information provided to me by Mr. Nasman and consulted with a senior Astra scientist who knew Mr. Nitenberg; I concluded that, under U.S. law, Mr. Nitenberg

was not an inventor.

*it is clear* to me that I gave an opinion to Mr. Nasman that Mr. Nitenberg was not an inventor

*it is clear* to me that I concluded that the information provided to me by Mr. Nasman, including the assertions he had made to Lejus that he considered Nitenberg to be an inventor under Swedish law, were not "material" under Rule 56 and need not be disclosed to the USPTO.

(emphasis added) (Declar. of Filardi ¶ 10) Also, "I believe that I discussed the question of inventorship with Astra's Peder Berntsson and Astra's Gerhard Miksche, both of whom happened to be in my New York City offices on another Astra matter." (Declar. of Filardi ¶ 12) These are not recollections of what happened but rather are a guess of what must have of happened in Filardi's opinion. I find that this declaration contradicts Filardi's deposition testimony about his recall of events and should be discounted. *See Dotson v. Delta Consol. Industries, Inc.*, 251 F.3d 780, 781 (8th Cir.2001) (a party may not create a question of material fact, and thus forestall summary judgment, by submitting an affidavit contradicting his own sworn statements in a deposition).<sup>FN14</sup>

FN14. I note here that Astra has maintained a pattern of submitting witness declarations that contradict their own deposition testimony. For example, compare Appelgren's deposition testimony that he could not recall the particulars of his meeting with Stenhede in Södertälje with his post-deposition declaration that he provided a list of salts to make which included metoprolol succinate. This declaration contradicts not only Appelgren's deposition responses but also the deposition of Astra's Rule 30(b)(6) witness, Ulf Jonsson, who stated that when he and Appelgren met with Stenhede they did not specifically direct him to make metoprolol succinate. A party cannot avoid summary judgment by filing a declaration that contradicts that party's Rule 30(b)(6) deposition testimony. *See Rainey v. American Forest and Paper Ass'n, Inc.*, 26 F.Supp.2d 82, 95 (D.D.C.1998). In his deposition, Lilljequist did not recall who suggested which salts of

Not Reported in F.Supp.2d

Page 18

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

metoprolol nor could he recall if he was given a list of salts to make. Yet he clearly stated that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). Yet in his post-deposition declaration he states that he did receive a list of salts to make that included metoprolol succinate. Similarly, in her deposition Eskilsson could not recall why she was a named inventor of metoprolol succinate. Yet in her post-deposition declaration she asserts that she did invent metoprolol succinate and the basis for her belief.

Even if I were to ignore Filardi's deposition testimony and I were to rely solely on Filardi's declaration, Filardi's conclusion that "there was no inventorship issue for the USPTO to decide" (Declar. of Filardi ¶ 12) is flawed because it is undisputed that Filardi was not provided with all of the facts or documents regarding the inventorship dispute. Two assumptions made by Filardi in his declaration highlight the lack of full disclosure made by Astra to Filardi which materially prevented Filardi from being fully apprised of the inventorship dispute.

The first assumption concerns the question of what Filardi was told about the inventorship dispute with Lejus regarding Appelgren and Eskilsson. In his declaration, Filardi states that he "does not recall being aware of *any information* that called into question whether Appelgren and Eskilsson were the true and correct inventors." (emphasis added) And that "*the only question raised by Astra* was whether, under U.S. law, Nitenberg should be *added* as an additional inventor ...." (emphasis added) (Declar. of Filardi ¶ 10)

\*22 The reason that Filardi's is not able to recall "any information that called into question" Appelgren's and Eskilsson's roles as inventors is that it is undisputed that Astra never gave Filardi copies of Nasman's letters to Ulf Inger dated February 12, 1988 and May 31, 1988. Astra's contention that Appelgren and Eskilsson did not invent metoprolol succinate was the subject of a long-running dispute between Astra and Lejus. As discussed above, Nasman's let-

ters clearly assert that Nitenberg is *the* inventor of metoprolol succinate and that Appelgren's and Eskilsson's inventorship "*should be limited* to the special form of pharmaceutical composition that is specified in Lejus' original application" which was claim 2 of the Swedish and United States applications. (emphasis added)

In addition, Astra initiated an action in the Swedish Patent Office asserting that Nitenberg was true inventor of metoprolol succinate and that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." (Defs.' Memo in Supp Ex. 11) It is undisputed that Astra did not give Filardi a copy of the Swedish Patent Office submission filed by Astra contesting the Lejus patent based on the dispute over inventorship. It is also undisputed that Astra did not provide Filardi with a copy of the agreement reached between Astra and Lejus regarding dividing up the patents.

Based on Filardi's "recollection" of events, it is apparent that he was not told the whole story of the long-running dispute between Astra and Lejus concerning who invented metoprolol succinate. Because Filardi "had no information that would cause [him] to question whether Appelgren and Eskilsson were the correct inventors ... there is nothing to indicate to [him] that any further "inquiry" into the issue was needed." *Id.* at ¶ 17. As a result of Astra's undisputed failure to fully disclose to Filardi Astra's position that Appelgren and Eskilsson did not invent metoprolol succinate, Filardi did not attempt to interview them or investigate the role of Stenhede and Lilljequist (the chemists at Södertälje) regarding its invention.

The second flawed assumption involves putting the horse before the cart or, at best, circular reasoning. In his declaration, Filardi states that it made no difference as to priority whether Nitenberg was added or not added [as an inventor to the U.S. application] as far as claiming priority on the January 1985 U.S. priority application. In either case, the '161 patent would have been entitled to at least the January 1985 U.S. priority date, which is prior to the July 1985 publication date of the Lejus Swedish application.

Not Reported in F.Supp.2d

Page 19

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

(Declar. of Filardi ¶ 18) Astra had not given Filardi a copy of the September 19, 1985, memorandum drafted by Wurm highlighting the fundamental issue that the "use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty reference" to any of Astra's future claims concerning metoprolol succinate. Because Filardi was not provided with the memorandum he was not informed of Wurm's concern that even a victory in the Swedish Patent Office regarding inventorship may be hollow because of the prior art effect of the Lejus publication.

**\*23** Without this information, Filardi could not have appreciated that Astra's later equivocation of the inventorship issue in January 1989 might need to be disclosed to the USPTO, or at a minimum, might require further investigation as to the true inventor of metoprolol succinate. Because Filardi's legal analysis was directed toward the sole issue of *adding* Nitenberg as an inventor in the '897 patent application, he not aware that there was a genuine dispute that Appengren and Eskilsson were improperly named inventors and that the '897 application may not be entitled to priority to the January 1985 United States application.

If Astra had prevailed with either the Swedish Patent Office or with Lejus in naming Nitenberg as the sole inventor of metoprolol succinate, the claim to metoprolol succinate (in the '161 patent application and in the '154 patent application) would not have been entitled to priority to the January 1985 United States application which listed only Appengren and Eskilsson as inventors. So Filardi's statement in his declaration that adding Nitenberg made no difference would be correct if either Appengren and Eskilsson were also still a named inventor. Filardi's statement would be incorrect, however, if Nitenberg replaced both Appengren and Eskilsson as the inventor. Astra did not give Filardi a chance to consider such a scenario because it failed to provide him with the complete facts concerning its three year dispute with Lejus about inventorship.

Based on the Astra's failure to fully disclose the inventorship dispute to Filardi, I find that Filardi was

prevented by Astra from considering information that would have led to a disclosure of the inventorship dispute to the USPTO.

Astra has submitted a declaration of then in-house counsel Nasman in opposition to summary judgment. Defendants assert that this evidence should not be considered based on Astra's failure to identify Nasman as a person with information regarding the inventorship dispute in Astra's Rule 26(a) disclosures and in responses to Defendants' discovery requests.

Even if I were to consider Nasman's declaration, however, it does not change my conclusion that he and Astra failed to be fully candid in providing information to Filardi so that Filardi could make informed decisions regarding the duty of candor and disclosure to the USPTO. Nasman's declaration states in a conclusory fashion that during the telephone call of January 11, 1989, Filardi provided him with advice on the issue of inventorship and that based on Filardi's advice Nitenberg "was not an inventor and that Mr. Appengren and Ms. Eskilsson were the proper inventors." (Declar. of Nasman at ¶ 17) Because Nasman and Astra failed to provide Filardi with all the information that Astra had regarding its concern with Lejus' July 17, 1985 publication and Astra's three-year inventorship dispute with Lejus (seeking not just to *add* Nitenberg to the patent applications but asserting that Nitenberg be named as *the* inventor of metoprolol succinate) Filardi's advice cannot be relied upon by Nasman to justify his conclusion concerning inventorship.

**\*24** Nasman's declaration further states that he concluded from his own investigation that Nitenberg should not be a named inventor. However, in his deposition taken after this declaration was made, Nasman states that his investigation consisted of (1) reviewing the Nitenberg lab protocol document, (2) reviewing the Lejus Swedish Application to which Astra claimed priority, and (3) talking to Filardi by telephone in January 1989. (Defs. Reply Memo. Ex. 11 at 66, 73, and 77) I need not consider the contradictions between Nasman's declaration and his deposition testimony. Whether Nasman conducted a minimally competent investigation as to who invented metoprolol succinate does not matter at this stage of

Not Reported in F.Supp.2d

Page 20

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

the lawsuit. In the present summary judgment context, the question of whether the correct inventors were named in the patents in suit is secondary because the undisputed question of inequitable conduct centers around the failure of Astra to inform the USPTO about its long-running inventorship dispute with Lejus. It is undisputed in the record that Nasman and Astra failed to fully disclose material information to its United States patent counsel, Filardi, concerning Astra's inventorship dispute with Lejus.

*A finding of inequitable conduct*

Contradictory evidence abounds concerning whether Appelgren and Eskilsson were the true inventors of metoprolol succinate. Although the contradictions are predominately created by Astra's post-deposition declarations and are subject to be discounted, enough material facts are in dispute to prevent summary judgment on the issue of whether Astra submitted false information regarding inventorship to the USPTO.

Clear and convincing evidence, however, has established that Astra and Lejus were engaged in an prolonged dispute over inventorship of metoprolol succinate and this dispute was not disclosed to the USPTO. The undisputed documents establish that the dispute regarding inventorship spanned more than a three-year period. Inventorship is very material information in a patent prosecution. There was a substantial likelihood that a reasonable examiner would have considered the inventorship dispute between Astra and Lejus important in deciding whether to allow the '161 and '514 patent applications to issue.

*Each individual* associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability as defined in this section. 37 C.F.R. § 1.56. "Close cases should be resolved by disclosure, not unilaterally by the applicant." *LaBounty Mfg., Inc. v. United States International Trade Commission*, 958 F.2d 1066, 1076 (Fed.Cir.1992). Disputes concerning inventorship are material information that need to be disclosed. *PerSeptive Biosystems, Inc.*, 225 F.3d at

1321.

On March 25, 1988, Lejus filed, on Astra's behalf, the '897 (which became the '161 patent and the '154 patent) naming Appelgren and Eskilsson as inventors. At that time Astra had been asserting to Lejus for more than two years that Nitenberg had solely invented metoprolol succinate through letters and by initiating an inventorship dispute with the Swedish Patent Office. *Even after the patent application was filed* Astra's counsel wrote to Lejus to demand that Nitenberg be listed as *the* inventor of metoprolol succinate in the European and United States patent applications filed per their agreement.

**\*25** Yet Lejus failed to disclose this long-running material dispute to the USPTO in its filing and prosecution of the '897 application. Nor did Astra disclose this information to the USPTO. Although Astra's United States patent counsel, Filardi, believed he made all of the disclosures necessary, Astra failed to provide him with important and material information concerning its dispute with Lejus. Astra cannot benefit from its failure to disclose material information to its United States patent counsel and then hide behind its argument that he acted in good faith and candor in his prosecution of the patent. It was Astra's own failure to disclose which led Filardi to believe he was disclosing all information known to be material to patentability. Astra's employee Nasman was an individual associated with the filing and prosecution of the patent application and had a duty of candor and good faith to the USPTO. Nasman was fully aware of the extent of the inventorship dispute. Nonetheless, Nasman and Astra failed to fully disclose the inventorship dispute with Lejus to Filardi which prevented the possibility of the dispute from being disclosed to the USPTO.

I do not believe that the question of whether to disclose the inventorship dispute was a close call. To find otherwise is to find that Astra's filing with the Swedish Patent Office and its three-year dispute with Lejus were pursued in bad faith.

Not only was the issue of the dispute of inventorship highly material, Astra had a strong incentive to not disclose the dispute. If a patent examiner had learned

Not Reported in F.Supp.2d

Page 21

Not Reported in F.Supp.2d, 2006 WL 120343 (E.D.Mo.)

(Cite as: Not Reported in F.Supp.2d)

of the dispute and found Nitenberg to be the sole inventor of metoprolol succinate, the '897 patent application would not have been entitled to priority to the January 1985 United States application. The effective filing date for the '897 patent would have been March 25, 1988. As a consequence, Astra's metoprolol succinate patents may have been denied as anticipated by the prior art of the publication of the Lejus' European application on July 17, 1985.

I find by clear and convincing evidence that the inventorship dispute between Astra and Lejus was highly material and should have been disclosed to the USPTO during the prosecution of the patents in suit. I also find by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol succinate inventions as anticipated by prior art. The intent to deceive is clearly present. After weighing materiality and intent I find that Astra's conduct was so culpable that its '161 patent and '154 patent are unenforceable.

#### *Conclusion*

I find by clear and convincing evidence that Astra's '161 patent and '154 patent are invalid on the basis of double patenting over the '318 patent. I also find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent application filing date. As a consequence I find that the '161 patent is invalid as anticipated.

\*26 Finally, I find by clear and convincing evidence that the '161 patent and '154 patent are unenforceable based on Astra's inequitable conduct in the prosecution of these patents in the United States Patent and Trademark Office. Astra failed to disclose to the USPTO the material dispute it had with Lejus concerning inventorship of metoprolol succinate. The failure to disclose was done with an intent to deceive the patent examiner as to this material dispute. Astra failed to provide material information in order to avoid questions concerning Astra's ability to claim priority to the '318 patent application and to avoid potential prior art concerning metoprolol succinate.

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion

for Summary Judgment of Invalidity [# 120] is GRANTED. Plaintiffs' Motion for Partial Summary Judgment of No Invalidity of United States Patent 5,081,164 for Double Patenting [# 297] is DENIED.

IT IS FURTHER ORDERED that Defendants' Motion for Summary Judgment Seeking a Declaration that United States Patent Nos. 5,001,161 and 5,081,154 are Unenforceable for Inequitable Conduct [# 241] is GRANTED.

IT IS FURTHER ORDERED that all other pending motions in this case are DENIED as moot.

E.D.Mo.,2006.

In re Metoprolol Succinate Patent Litigation

Not Reported in F.Supp.2d, 2006 WL 120343

(E.D.Mo.)

END OF DOCUMENT